EXHIBIT C15

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES AND PRODUCTS LIABILITY LITIGATION	:	Civil Action No. 3:16-md-2738-FLW-LHG

EXPERT REPORT
DAVID A. KESSLER, M.D.

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SCHEDULES[1]

APPENDICES

[1] The schedules were prepared by legal staff at my direction and under my review.

I. QUALIFICATIONS

1. My name is David A. Kessler, M.D. I received my M.D. degree from Harvard Medical School in 1979 and my J.D. degree from the University of Chicago Law School in 1978.

2. I did my pediatrics training at Johns Hopkins Hospital.

3. In 1990, I was appointed by President George H. W. Bush as Commissioner of the United States Food and Drug Administration ("Commissioner") and was confirmed by the United States Senate. I also served in that position under President William Jefferson Clinton until February 1997.

4. I have taught food and drug law at Columbia University Law School, and I have testified many times before the United States Congress on food, drug, and consumer protection issues under federal and state law. Over the last thirty years, I have published numerous articles in legal, medical, and scientific journals on the federal regulation of food, drugs, and medical devices. I have had special training in pharmacoepidemiology at Johns Hopkins Hospital. My resume is attached as Appendix A. A list of cases in which I have appeared as an expert witness in the last four years, and documentation of my expert witness fee, is attached as Appendix B.

5. As Commissioner, I had ultimate responsibility for implementing and enforcing the United States Food, Drug, and Cosmetic Act (the "Act"). I was responsible for overseeing five Centers within the FDA. They included, among others, the Center for Drug Evaluation and Research, the Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research. In addition to those duties, I placed high priority on getting promising therapies for serious and life-threatening diseases to patients as quickly as possible. During my tenure as Commissioner, the FDA announced a number of new programs including: the regulation of the marketing and sale of tobacco products to children; nutrition labeling for food;

user fees for drugs and biologics; preventive controls to improve food safety; measures to strengthen the nation's blood supply; and the MEDWatch program for reporting adverse events and product problems involving both drugs and devices. I created an Office of Criminal Investigation within the Agency to investigate suspected criminal violations of the Act, FDA regulations and other related laws. While I was Commissioner, I attempted to institute a voluntary reporting system of adverse events from cosmetics. The cosmetic industry, through its association, vigorously opposed such regulation.

6. I am a senior advisor to TPG Capital, a leading global private equity firm, which owns pharmaceutical and biomedical companies. I served on the board of Aptalis Pharma. I currently serve on the boards of Stoke Pharmaceuticals, Tokai Pharmaceuticals and the medical device and biologics company Immucor, Inc. In these advisory and fiduciary capacities, I have advised companies on the standards and duties of care within the pharmaceutical and medical device industry. I also chaired the compliance committee of Aptalis Pharma, and currently chair the quality committee at Immucor, Inc., which involves ensuring compliance with the FDA's regulations and requirements.

7. The documents provided to me by counsel, or that I accessed independently from various sources, including, but not limited to, the FDA's website, are attached as Appendix C. At my request, and subject to my directions and review, the attached Schedules were prepared by legal staff. Based on my review of the documents listed in Appendix C, and my training and experience, I have a number of opinions that are detailed below.

8. It is my understanding that the cases included in this litigation include, but are not limited to, the following claims as they relate to talcum powder products:

a. Negligence;

b. Negligent Misrepresentation;

c. Strict Products Liability – Failure to Warn;

d. Strict Product Liability – Defective Manufacture and Design;

e. Breach of Express Warranties;

f. Breach of Implied Warranty of Merchantability;

g. Breach of Implied Warranty of Fitness for a Particular Purpose

h. Fraud;

i. Fraudulent Concealment;

j. Violation of Consumer Protection Laws;

k. Civil Conspiracy

l. Loss of Consortium

m. Punitive Damages

n. Discovery Rule and Tolling

o. Wrongful Death

p. Survival Action[2]

9. In this report, I use the term "Defendants" to refer to one or more of the following corporate entities, including Johnson & Johnson; Johnson & Johnson Consumer Inc. f/k/a Johnson & Johnson Consumer Companies, Inc.; Imerys Talc America, Inc., f/k/a Luzenac, Inc., f/k/a Rio Tinto Materials, Inc.; and Personal Care Products Council ("PCPC") f/k/a Cosmetic, Toiletry, and Fragrance Association ("CTFA").

10. The plaintiffs in this case consist of all current plaintiffs in or subsequently added to MDL No. 3:16-md-2738-FLW-LHG. It is my understanding that the plaintiffs in this litigation

[2] See Plaintiffs First Amended Master Long Form Complaint and Jury Demand for MDL 3:16-md-2738-FLW-LHG, Dkt. 132 filed March 16, 2017.

have been diagnosed with various forms of cancer of the female reproductive system, including ovarian cancer, cancer of the fallopian tube, and primary peritoneal cancer.[3]

11. Talcum powder products can be regulated as either drugs or cosmetics depending on their intended use and the claims that are made for the product. Talc may also be used as an inactive ingredient in a number of regulated products. It has also had certain historical uses as a food and color additive and in medical devices. It is my understanding that the products at issue in this matter have been regulated as cosmetic. Schedule 1 provides a brief FDA regulatory chronology for talcum powder products as cosmetic. Schedule 2 provides various regulatory standards for the composition of talcum powder products. Schedule 3 provides examples of the various FDA regulated talc-containing products.

12. My opinions in this case focus on the responsibilities of cosmetic manufacturers, focusing on the regulatory interface between cosmetic manufacturers and the FDA, as well as industry standards. I have not been asked to opine on the scientific evidence concerning an association between the use of talcum powder products and ovarian cancer. I have been asked to address the duties of cosmetic manufacturers to warn in the face of a potential health hazard.

II. COSMETIC MANUFACTURES HAVE THE RESPONSIBILITY TO SUBSTANTIATE THE SAFETY OF THEIR PRODUCTS PRIOR TO MARKETING

A. The regulatory standards for cosmetics

13. Unlike drugs, the Federal Food Cosmetic Act does not require the premarket approval of cosmetics.

[3] *Id.*

14. FDA promulgated regulations on March 3, 1975, which remain in effect today that require that, "[e]ach ingredient used in a cosmetic product and each finished cosmetic product shall be adequately substantiated for safety prior to marketing." 21 CFR §740.10

15. The regulations further state that, "[a]ny such ingredient or product whose safety is not adequately substantiated prior to marketing is misbranded unless it contains the following conspicuous, statement on the principal display panel: Warning-The safety of this product has not been determined." 21 CFR §740.10

16. A manufacturer who has not adequately substantiated the safety of their cosmetic product or their ingredients cannot ship their product in interstate commerce. 21 USC §331(a)

17. In addition, a manufacturer of a cosmetic product must assure that the cosmetic's label "shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product." 21 CFR §740.10.

18. The regulations also state that, "[a]n ingredient or product having a history of use in or as a cosmetic may at any time have its safety brought into question by new information that in itself is not conclusive. The warning required by paragraph (a) of this section is not required for such an ingredient or product If: (1) The safety of the ingredient or product had been adequately substantiated prior to development of the new information; (2) The new information does not demonstrate a hazard to human health; and (3) Adequate studies are being conducted to determine expeditiously the safety of the ingredient or product."[4] 21 CFR §740.10(b) [emphasis added].

19. A cosmetic is adulterated if it bears or contains, "any poisonous or deleterious substance which may render it injurious to users." 21 USC §361.

[4] The regulation continues, this requirement ". . . does not constitute an exemption to the adulteration provisions of the act or to any other requirement in the act or this chapter." 21 USC 740.10 (c).

20. In my opinion, of all the products that fall under FDA's jurisdiction, cosmetics are among the least regulated. This is reflected in the fact that there is no premarket approval of cosmetic products.

21. Moreover, only very limited resources have ever been committed to cosmetic product review, monitoring, or safety.

22. The limited oversight of cosmetics products has been recognized.

23. In, 1978 the United States General Accounting Office (GAO) "concluded that the effectiveness of FLN'S regulatory actions was limited by inadequacies in both FDA'S legislative authority and the industry's participation."[5]

24. In March 1990, the GAO reported to the Subcommittee on Regulation, Business Opportunities, and Energy that the "FDA's regulatory authority over the cosmetics industry is less comprehensive than its authority over food and drugs. Consequently, in its oversight of the cosmetics industry, FDA must rely, in part, on voluntary industry cooperation . . . FDA does not have authority to require the industry to do safety testing and injury reports. FDA must rely on manufacturers to volunteer the data and reports. FDA officials have found that many manufacturers lack adequate data on safety tests and have generally refused to disclose the results of these tests . . . Finally, FDA has been studying the industry report on toxic chemicals used in cosmetics, but has committed no resources to do its own safety reviews and ranking."[6]

25. In their 2017 article, Robert Califf, et al. wrote, "[t]he debate about regulation of the cosmetics industry to protect the public health has gone unresolved for more than a century . . . The challenge for regulators is daunting; the global cosmetics industry is enormous, with an

[5] Cosmetics Regulation. Information on Voluntary Actions Agreed to by FDA and the Industry. (GAO/HRD-90-58, Mar. 1990), citing Lack of Authority Hampers Attempts to Increase Cosmetic Safety. (GAO/HRD-78-139, Aug. 1978).
[6] *Id.*

expected $265 billion in revenue in 2017. The Office of Cosmetics and Colors within the FDA's Center for Food Safety and Applied Nutrition [CFSAN] is tiny in contrast and, with a budget of around $13 million for Fiscal Year 2017, chronically underfunded, even considering its limited responsibilities and scope of authority . . . History has repeatedly shown that when there is insufficient regulatory oversight, a few unscrupulous people or companies will exploit the vulnerable public for profit . . . [a]lthough FDA oversight of drugs and medical devices has been substantially strengthened by later legislation, the lack of similar enhancements for cosmetics means that the cosmetic industry remains largely self-regulated . . .For cosmetics—and for dietary supplements—the FDA's oversight authority remains stuck at the levels established in 1938, nearly 80 years ago . . . The FDA is vastly underresourced for even the very limited responsibility it currently has for the safety of cosmetics."[7]

26. In 2017, Kwa, et al. wrote, "[b]etter cosmetic surveillance is needed given their ubiquity and lack of a premarket approval pathway. Unlike devices, pharmaceuticals, and dietary supplements, cosmetic manufacturers have no legal obligation to forward adverse events to the FDA; CFSAN reflects only a small proportion of all events. The data suggest that consumers attribute a significant proportion of serious health outcomes to cosmetics. The lack of high-quality data leads to reactionary responses by the FDA subject to consumer pressure."[8]

27. In July 2018, Senators Dianne Feinstein and Susan Collins wrote in the Journal of the American Medical Association, "[t]here is no other class of products so widely used in the

[7] Califf, Robert M., Jonathan McCall, and Daniel B. Mark. "Cosmetics, Regulations, and the Public Health: Understanding the Safety of Medical and Other Products." JAMA Internal Medicine 177, no. 8 (August 1, 2017): 1080–82. https://doi.org/10.1001/jamainternmed.2017.2773.

[8] Kwa, Michael, Leah J. Welty, and Shuai Xu. "Adverse Events Reported to the US Food and Drug Administration for Cosmetics and Personal Care Products." JAMA Internal Medicine 177, no. 8 (August 1, 2017): 1202–4. https://doi.org/10.1001/jamainternmed.2017.2762.

United States with so little regulation . . . [t]he lack of oversight is a broad threat to public health . . . As a result, US companies that market personal care products largely determine their own safety standards."[9]

28. On November 11, 2008, Anna Prilutsky, then Senior Director Research & Development at Johnson & Johnson, sent a PowerPoint from Lori Dolginoff, then Director, Global Communications at Johnson & Johnson, containing "the latest version of the content for the Pure Truth website" which stated on a slide titled "Ingredients in JOHNSON's Baby products" that there is "[l]imited role of FDA." JNJ000367482-3.

29. In a December 2013 PowerPoint presentation, Defendant Imerys stated "[c]osmetics are different from foods and drugs and are governed by much looser regulation . . . Companies are in charge of performing the analysis and conforming to the standards. The FDA requires no prior testing for cosmetic products." IMERYS 068497.

30. A 2009, Johnson & Johnson memorandum regarding "Cosmetics Regulation" stated that "the oversight of the FDA is secondary to individual company responsibility to self-regulate in meeting these standards." JNJTALC00494340.

31. The memorandum continued, "[v]oluntary self-regulation of the cosmetics industry in the United States is not working. Consumers deserve a government that protects them from unsafe chemical exposures in the cosmetics they use every day." JNJTALC000494340 at 49.

32. In my opinion, a cosmetic manufacturer has a responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined.

33. In my opinion, in addition, if a health hazard may be associated with the product, a cosmetic manufacturer must include a warning on their product.

[9] Feinstein, Dianne, and Susan Collins. "The Personal Care Products Safety Act." JAMA Internal Medicine 178, no. 5 (May 1, 2018): 601–2. https://doi.org/10.1001/jamainternmed.2018.0064.

34. In my opinion, the federal regulation of cosmetics is less stringent than the regulation of drugs, medical devices, and food additives. FDA's oversight of cosmetics is also limited by resource constraints.

B. The standards in the cosmetic industry to substantiate the safety of cosmetic products

35. Defendants have been long standing members of the Personal Care Products Council (formerly the CTFA). Deposition of Mark Pollack, August 29, 2018. 44:7-45:6; 62:15-64:2; 105:13-18; 110:12-21; 128:10-21; Prepared Statement of Pamela G. Bailey, President Personal Care Products Council, May 14, 2008, United States House of Representatives Committee on Energy and Commerce.

36. The CTFA established the Cosmetic Ingredient Review in 1976. "The Cosmetic Ingredient Review (CIR) was established in 1976 by the industry trade association with the participation of the U.S. Food and Drug Administration and the Consumer Federation of America. The CIR is the industry funded panel that (reviews?) the safety of the ingredients used in cosmetics today. Its meetings are open to the public and its findings and minutes are publicly available on its website. FLDI Primer on Cosmetic Regulation, P. 12, PCPC_MDL00000998 at 1012.

37. According to the CIR, the purpose of such review is, "is to determine those cosmetic ingredients for which there is a reasonable certainty in the judgment of competent scientists that the ingredient is safe under its conditions of use." [emphasis added] CIR Procedures Report June 2018, at 3.

38. The CIR has stated, "Safe" or "safety" means no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future, e.g., a

low incidence of minor adverse reactions (as shown in animal or human testing or product experience). Such information includes, but is not limited to, the chemical structure of the ingredient, published and unpublished tests on the ingredient and products containing the ingredient, significant human experience on products containing the ingredient during marketing, and information on similar or related substances. A lack of information about an ingredient shall not be sufficient to justify a determination of safety." [emphasis added] CIR Procedures Report June 2018, at 2.

39. Executive Vice President and Legal and General Counsel Elizabeth H. Anderson and Associate General Counsel Farah K. Ahmed or the Personal Care Products Council authored the 2012 Food and Drug Law Institute's Primer on the Cosmetic Regulatory Process which states, "[c]osmetics are not subject to premarket approval by the Food and Drug Administration (FDA), but the product and ingredients must be tested for safety. If the manufacturer cannot substantiate safety, a warning is required . . . The "intended use" doctrine states that cosmetic or drug status is determined by claims about the intended use of the product." PCPC_MDL00000998 at 1004.

40. In my opinion, consistent with FDA regulations and statutes, a cosmetic manufacturer under the cosmetic industry standards must assure the safety of their ingredients. It is the responsibility of the cosmetic manufacturer to assure that there is reasonable certainty in the judgment of competent scientists that the product is safe. Safe as defined by the industry standards means "no evidence in the available information that demonstrates or suggests reasonable grounds to suspect a hazard to the public under the conditions of use that are now current or that might reasonably be expected in the future . . .". Cosmetic Ingredient Review Procedures, October, 2010/June 2018 Part A – General, Section 1. Definitions. (m).

41. Thus, in my opinion, manufacturers have a responsibility to assure that there is reasonable certainty there is no evidence to suspect their cosmetic may pose harm. Furthermore, in my opinion, if there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such product does not meet the industry standards for safety.

C. Defendants' statements that cosmetic manufacturers have responsibility to substantiate the safety of their product.

42. On January 26, 1994, Dr. Stephen D. Gettings, Director-Toxicology of the CTFA sent a final draft of a manuscript for presentation at a symposium[10] to the "Talc Interested Party Task Force", which included Dr. William Ashton and Michael Chudkowski (both at Johnson & Johnson), as well as Dennis Christensen and Richard Zazenksi (both at Luzenac America, Inc., now Imerys). Dr. Gettings thanked the Talc Interested Party Task for members "for all your help" and stated he still had questions that he needs answered before he gives the presentation. In the attached manuscript, Dr. Gettings stated, "In the United States, the safety of cosmetic ingredients and finished formulations must be substantiated by manufacturers. Raw material suppliers also bear a responsibility for the safety substantiation of ingredients they supply to the cosmetic industry since Section 201(i) of the FD&C Act defines 'cosmetic' to include articles used as components of cosmetic products (21 U.S.C. 321(i))." IMERYS-A_0005946.

43. Dr. Gettings further stated, "The talc industry has a moral and legal responsibility to supply products that can be used safely . . . Talc facilities engaged in the manufacture of USP, FCC, or CRFA-grade talc products are subject to the general provisions of the FDC&C Act and

[10] The symposium, "Workshop on Talc: Consumer Uses and Health Perspectives" was held on January 31, 1994 at the National Institutes of Health. IMERYS_00057325.

are prohibited from introducing adulterated articles into interstate commerce . . .” IMERYS-A_0005946.

44. In a June 24, 2003 PowerPoint Johnson & Johnson stated that Johnson’s Baby products are “assessed for safety based on the intended use.” JNJTALC000777136.

45. On November 11, 2008, in the aforementioned email and PowerPoint presentation sent by Anna Prilutsky, Senior Director Research & Development at Johnson & Johnson, Defendant stated, “The FDA requires an ingredient declaration on the product’s packaging to enable you to make informed purchasing decisions . . . The FDA also requires that each ingredient used in personal care products and each finished product be adequately substantiated for safety prior to marketing. FDA regulations do not have prescriptive tests that manufacturers are required to follow to substantiate safety. The responsibility for determining and conducting appropriate tests to substantiate safety is that of the manufacturer. Furthermore, if the safety is not substantiated, the label must bear the statement: *Warning – The safety of this product has not been determined.*” .JNJ000367482-3.

46. The same PowerPoint continued, “Our baby products are composed of a variety of ingredients obtained from reputable, trusted suppliers. We hold these suppliers to high standards of material safety, purity and quality based on our best for baby standards. The safety and quality of these materials are critical to the success – how well they meet your needs – and safety of the final products. When we acquire raw materials and active ingredients from our suppliers, we don’t simply take their word for the safety of ingredients. We rely on validated scientific proof of safety for individual ingredients and finished products. Every lot of every raw material is evaluated before it is released for use in any finished product. And we ensure that all ingredients

comply fully with regulations in all countries where our baby products are sold." JNJ000367483.

47. In a June 1, 2010, PowerPoint presentation, sent by David Stanavage, then Senior Product Director, Johnson & Johnson and Kathleen Wille, Manager, Regulatory Affairs, Johnson & Johnson and meant to address concerns raised by retailer Walmart about what was "best for baby" stated that it "assessed each ingredient that we consider for use in our personal care products for baby." JNJ 000438939-41. The PowerPoint continues, "[a]ll final baby product formulations are comprehensively assessed for safety . . . Johnson's Brand is responsible for the ethical management of health, safety, and environmental aspects of our products through their total lifecycle." JNJ 000438939-41.

48. The PowerPoint continued, "the FDA has limited resources and enforces according to the risk to public health. The FDA does not pre-approve personal care product labeling prior to marketing. It is the manufacturer's responsibility to ensure that labeling is accurate. We follow strict rules for nomenclature to ensure an accurate representation of the contents of our products." JNJ 000438941.

49. On October 15, 2012, Lorena Telofski testified on behalf of Johnson & Johnson that Johnson & Johnson goes "through a process to substantiate safety for the present use. If it doesn't meet the threshold of safety for present use, it is not going to go on the market." 201:198-23; *see* also 199:21-23.

50. On December 16, 2014, Jay Ansell, Vice President – Cosmetics Program, Personal Care Products Council (Formerly CTFA), sent an email stating his "primary concern" regarding the statement in a "Frequently Asked Questions" document for the Look Good Feel Better

Program[11] that, "Cosmetic Ingredients are not required by federal or state laws to be tested for their contributions to the risks of acquiring cancer or other adverse health conditions from long-term use." Ansell continued that "While it is true that Federal law does not require 'Testing', Federal law absolutely requires the safety be substantiated. 21 CFR 740.10(a)." PCPC_MDL00122041.

III. THE DEFENDANTS DID NOT SUBSTANTIATE THE SAFETY OF THEIR TALCUM POWDER PRODUCTS

51. As noted above, according to industry standards, if there is evidence that there are reasonable grounds to suspect that the cosmetic product may pose harm for the proposed conditions of use, such products do not meet the industry standards for safety.

52. Further, as noted above, FDA regulations require that a cosmetic manufacturer has a responsibility to substantiate the safety of their product or must warn consumers that the safety of their product has not been determined.

53. The safety of a cosmetic, as is the case for other FDA regulated products, needs to be determined "under such conditions of use that are customary or usual . . ."[12] Thus, it is not the safety of talc that is determinative, rather it is the safety of talc as it is in fact used. Thus safety needed to be substantiated for talcum powder products that come into contact with the perineum/genital area.

A. FDA's 2014 Citizen's Petition Response stated there was some evidence to suspect or question the safety of talcum powder products

[11] According to the Personal Care Products Council, the Look Good Feel Better program is offered as a collaboration of the Personal Care Products Council Foundation, the American Cancer Society, and the Professional Beauty Association that "teaches cancer patients how to cope with the appearance (related) side-effects of cancer treatment. PCPC_MDL00122043.

[12] Section 601 of the FD&C Act [21 U.S.C. 361]

54. In its 2014 response to the 1994 and 2008 Citizen's Petitions, the FDA stated, ". . epidemiologic data [] show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder. While the growing body of evidence to support a possible association between genital talc exposure and serous ovarian cancer is difficult to dismiss, the evidence is insufficient for FDA to require as definitive a warning as you are seeking."[13] Steven M. Musser, Ph.D., letter to Samuel S. Epstein, April 1, 2014.

55. The FDA's response continued, "While there exists no direct proof of talc and ovarian carcinogenesis, the potential for particulates to migrate from the perineum and vagina to the peritoneal cavity is indisputable. It is, therefore, plausible that perineal talc (and other particulate) that reaches the endometrial cavity, Fallopian Tubes, ovaries and peritoneum may elicit a foreign body type reaction and inflammatory response that, in some exposed women, may progress to epithelial cancers."

56. I leave it to other experts to discuss the strengths, weaknesses, and specifics of the scientific evidence. FDA's statement that "epidemiological data which show a statistically significant but modest increased risk of epithelial ovarian cancer, especially with serous histology, among women with a history of genital dusting with talcum powder," while not supporting, in FDA's opinion, the petition's request for a "definitive" warning, demonstrates that the safety of talcum powder products was in question. Schedule 4 provides a summary of epidemiologic studies concerning the association of talcum powder products and ovarian cancer.

57. Searches of PubMed for "talc and ovarian cancer" and "body powders and ovarian cancer" demonstrates that since the FDA response to the citizens petition in 2014 there are

[13] The FDA response reviewed data dating back to at least 1961 and performed an expanded literature search from 2008-2014.

nineteen (19) publications of original data including meta-analyses, clinical studies, clinical trials, systematic reviews, and observational studies.[14]

58. I reviewed the abstracts from these 19 articles. From those, I selected all epidemiological studies, including case-control studies (3), cohort studies (2), and meta-analyses (2) relating to talcum powder usage and the risk of ovarian cancer.

59. Again, while I leave it to other experts to discuss the strengths, weaknesses, and specifics of the scientific evidence, these studies demonstrate that since the 2014 petition response, there is additional evidence to question the safety of talcum powder products.

a. A meta-analysis published by Berge et al. "resulted in a weak but statistically significant association between genital use of talc and ovarian cancer, which appears to be limited to serous carcinoma." However, the authors concluded: "Several aspects of our results, including the heterogeneity of results between case-control and cohort studies, and the lack of a dose-response with duration and frequency of use, however, do not support a causal interpretation of the association." (Berge 2017)

b. Another meta-analysis published by Penninkilampi and Eslick found that "[any] perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with ever use of talc was found in case-control studies (OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association

[14] The searches yielded seventeen (17) and two (2) articles respectively.

between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55).” This is the most common type of ovarian epithelial cancer. (Penninkilampi 2018)

c. Regarding a potential mechanism for the observed increased risk, Penninkilampi and Eslick state “[t]he mechanism by which perineal talc use may increase the risk of ovarian cancer is uncertain. It has been previously proposed that talc, as a foreign body, may ascend from the vagina through to the uterine tubes and instigate a chronic inflammatory response, which may predispose to the development of ovarian cancer. It is argued that cellular injury, oxidative stress, and local increase in inflammatory mediators such as cytokines and prostaglandins may be mutagenic and hence promote carcinogenesis. . . . If chronic inflammation due to ascending foreign body is indeed the mechanism by which talc use is associated with increased ovarian cancer risk, then these results fit the picture.” *Id*.

d. Using four case-control studies, Wu et al., examined six “well-accepted” risk factors for invasive epithelial ovarian cancer, including talc use, among Hispanics, African-Americans, and non-Hispanic whites. The population attributable risk percentage (PAR%) estimate was “12.2% to 15.1% for using talc in the three groups.” The combined OR with talc use was 1.46 (95% CI 1.27-1.69 (Wu 2015).

e. In a study of African American women from Schildkraut et al., “[g]enital powder was associated with an increased risk of [epithelial ovarian cancer] EOC (OR = 1.44; 95% CI, 1.11-1.86) and a dose-response relationship was found for duration

of use and number of lifetime applications ($P < 0.05$)." The authors concluded that "[t]he results support that body powder is a modifiable risk factor for EOC among AA women."

f. Regarding mechanism, Schildkraut et al. stated that their results "are consistent with localized chronic inflammation in the ovary due to particulates that travel through a direct transvaginal route. The dose-response observed for duration of genital powder use provides further evidence for the relationship between genital powder and overall EOC risk."

g. In a case-control and pooled study from Cramer et al., overall, "genital talc use was associated [with EOC] with an OR (95% CI) of 1.33 (1.16, 1.52) with a trend for increasing risk by talc years." The authors stated that "[t]hese observations provide a framework for talc carcinogenicity in EOC involving chronic inflammation. (Cramer 2016).

60. Two studies failed to find a statistically significant association (Houghton, Gonzalez)

61. In my opinion, based on FDA's analysis to the citizens petitions and the medical literature since FDA's 2014 petition response, there is scientific evidence to suspect or question the safety of talcum powder products.

B. The International Association for Research on Cancer (IARC) concluded that there was evidence of talcum powder's carcinogenicity.

62. In 2010, IARC published Monograph 93, which found that "[t]he relative risks for ovarian cancer among users of body powder (versus non-users) were homogenous across this relatively diverse set of eight studies, each of which indicated a 30–60% increase in risk . . . Perineal use of talc-based body powder *is possibly carcinogenic to humans (Group 2B).*" "IARC

Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 93," 2010.[15] This monograph specifically addresses the safety of talc not containing asbestiform fibers.

63. In regards to asbestos, talc containing asbestos, and talc containing asbestiform fibers (fibrous talc), IARC published Monograph 100c, which found that, "[t]here is *sufficient evidence* in humans for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite, and anthophyllite). Asbestos causes mesothelioma and cancer of the lung, larynx, and ovary . . . There is *sufficient evidence* in experimental animals for the carcinogenicity of all forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite). All forms of asbestos (chrysotile, crocidolite, amosite, tremolite, actinolite and anthophyllite) are *carcinogenic to humans (Group 1).*" "IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Volume 100c," 2012. "The conclusions reached in this *Monograph* about asbestos and its carcinogenic risks apply to these six types of fibres wherever they are found, and that includes talc containing asbestiform fibres."[16]

C. Defendants failed to substantiate the safety of their talcum powder products

64. In my opinion, in light of a) the FDA's 2014 petition response acknowledging that there remains some evidence to suspect or question the safety of talcum powder products, b) the medical literature since 2014 that continues to raise safety questions; and c) IARC's classification, defendants failed to substantiate the safety of their talcum powder products.

[15] IARC looked at data dating from at least 1933.
[16] *Id.* It is my understanding that other experts will discuss the specific aspects of asbestos and talc with asbestiform fibers (fibrous talc).

D. Defendants failed to warn consumers that the safety of their talcum powder products had not been determined

65. In my opinion because defendants failed to substantiate the safety of their talcum powder products, they should have warned consumers that the safety of their talcum powder products had not been determined.

IV. IN ADDITION TO THE WARNING THAT THE SAFETY OF TALCUM POWDER PRODUCTS HAS NOT BEEN ESTABLISHED, A WARNING ABOUT AN ASSOCIATION BETWEEN TALCUM POWDER AND OVARIAN CANCER WAS REQUIRED IF CERTAIN STANDARDS WERE MET

66. For purposes of my report, I defer to other experts who will discuss the association between talcum powder and ovarian and other forms of cancer.

67. As noted above, the FDA regulations require a warning if, "a health hazard may be associated with the product." 21 CFR §740.10

68. In my opinion the regulatory standard is less stringent than proof of a causal association. It does require that there is a reasonable basis to believe that such an association exists.

69. Labeling violations may include failure to warn consumers of potential health risks. Section 601(a) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. § 361(a)] and 602(a) of the Act [21 U.S.C. § 362(a)], which provides:

> "Section 601(a) of the Act [21 U.S.C. § 361(a)] a cosmetic is adulterated if it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or, under such conditions of use as are customary or usual.
>
> "602(a) of the Act [21 U.S.C. § 362(a)], a cosmetic is misbranded if its labeling is false or misleading in any particular. Section 201(n) of the Act [21 U.S.C. § 321(n)] provides that, in determining whether a product's labeling or advertising is misleading "there shall be taken into account (among other things) the extent to which the labeling or advertising fails to reveal facts material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual."

70. In my opinion, if there is a reasonable basis for an association between talcum powder products and ovarian cancer, a warning about increased risks of ovarian cancer needed to be made.

V. TALCUM POWDER PRODUCTS WOULD BE ADULTERATED UNDER THE FEDERAL FOOD DRUG AND COSMETIC ACT IF THEY CONTAINED POISONOUS OR DELETERIOUS SUBSTANCES.

71. A cosmetic is adulterated if it bears or contains, "any poisonous or deleterious substance which may render it injurious to users." 21 USC §361.

72. While as noted above other experts will testify to the presence and toxicity of asbestos and asbestiform fibers (fibrous talc) in talcum powder, it is my opinion that if asbestos or asbestiform fibers (fibrous talc) were found in talcum powder products, talcum powder products would be adulterated under the Federal Food Drug and Cosmetics Act.

73. Asbestos and talc with asbestiform fibers (fibrous talc) are known human carcinogens. (IARC 2012).

74. In my opinion, presence of asbestos in talcum powder products would meet the standards for adulteration since asbestos "may render [the product] injurious to users . . ." 21 USC §361.

David Kessler, MD

November 16, 2018
Date

SCHEDULE 1: BRIEF REGULATORY HISTORY OF COSMETIC TALCUM POWDER PRODUCTS

1894 Johnson's "Generally Regarded as Safe" (GRAS's Baby Powder introduced in the marketplace.[17]

1965 FDA designates talc as "Generally Regarded as Safe" or "GRAS" as a food additive.[18]

1967 Graham and Graham propose asbestos as etiologic factor in ovarian cancer.[19]

1971 Henderson identified talc particles embedded in ovarian tumor tissue.[20]

1972 J&J test results demonstrating presence of asbestos in Shower to Shower product sent to FDA.

> In 1972, Professor Lewin, a chemist at New York University, tested 102 commercial products for the presence of asbestos, including cosmetic talcum powder products. One of the products tested was J&J's Shower to Shower. The results were submitted to the FDA noting a finding of "5%" chrysotile asbestos in "sample 84" of Shower to Shower.[21] The FDA's testing (by optical microscopy) confirmed that "Sample No. 84 contained 107 fibers of tremolite/actinolite per milligram."[22]

1974 Talc/Asbestos Meeting with Commissioner Schmidt, FDA and J&J (1/16/1974)

"We traced the history of the talc/asbestos problem. . . Our very preliminary calculation indicates that substantial asbestos can be allowed safely in a baby powder. . . Dr. Schmidt. . . pointed out that additional information being developed by Johnson & Johnson and others would meet the possible future need if talc per se is attacked."[23]

1974 J&J to FDA: "Talc with 1% asbestos is safe."[24]

> Letter to Robert M. Schaffner, Associate Director for Technology, Bureau of Foods, FDA: "Johnson and Johnson has been cooperating with the Cosmetic, Toiletry and Fragrance Association Subcommittee on Asbestos in Talc. In an effort to answer the question for asbestos in talc, our statistical group has made an estimation of a theoretical safe level of asbestos and the data on dusting of baby powder. The calculation shows that a substantial safety factor can be expected with talc containing 1% w/w asbestos fibers. Therefore, methods capable of determining less than 1% asbestos n talc are not necessary to assure the safety of cosmetic talc."

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[17] Margaret Gurowitz, April 30, 2007. (Kilmerhouse.com.)
[18] 30 Fed. Reg. (Dec. 23, 1965)
[19] Graham and Graham
[20] Henderson (1971)
[21] August 3, 1972 Letter from S. Lewin to A. Weissler,
[22] FDA Memorandum for Project 00679, dated 9/6/73
[23] JNJ000259267
[24] JNJ000377123

1976 CTFA: Asbestiform Amphibole Minerals in Cosmetic Talc Methodology for Testing (J4-1)

> The method which has been adopted for the detection of amphibole minerals in cosmetic talc is the generally accepted method of x-ray diffraction. Methods which appear in the literature for the detection of fibrous amphibole, such as, transmission electron microscopy with selected area diffraction1 and electron microprobe, have also been considered since they are capable of a lower level of detection than by x-ray diffraction. However, they have not been adopted since they suffer from the drawbacks, that the amount of material under examination is quite small (less than a microgram) and the time for analysis, expertise required, and expense of equipment eliminates them as routine methods.[25]

1977 An FDA Update on the Asbestos Question

> "It now appears that several years may be required to fully clarify some of the scientific questions on this subject. In the meantime it may be prudent to establish by regulation a standard for all to follow. No doubt this approach will be questioned in the absence of widespread gross contamination."[26]

1977 Comparison between CTFA JD-4 method and FDA method

> At a CTFA Technical Administration Committee Meeting on February 1. 1977, the CTFA Standard (J4-1) for talc detection was published and distributed to FDA. The method was compared to the proposed FDA method. CTFA was qualitative; FDA was quantitative. CTFA had sensitivity to 0.5; FDA had sensitivity to 0.1. [27]

1978 Aerosol anti-perspirants safe

> **"**The charge to this Panel was to evaluate the safety and effectiveness of antiperspirant drug products. . . Talc is a magnesium silicate which is sometimes found to contain two groups of asbestos minerals: the serpentine and amphibole groups. It is these asbestiform minerals which are associated with the toxic effects of talc. The talc used in antiperspirant products is devoid of any asbestiform fibers. . .the Panel concluded that there is virtually no risk from asbestos in aerosolized talc in the amounts found in antiperspirant products if the material is determined to be free of asbestos by the Cosmetics, Toiletry and Fragrance Association, Inc. . . The Panel did not consider the safety of talc in products other than antiperspirants."[28]

[25] PCPC_MDL00007392-7401
[26] LoGiudice/WCD/0523
[27] JNJ000038327
[28] Federal Register 10/10/1978, 46695-46711

1978 A Public Citizen letter to Dr. Donald Kennedy, Commissioner FDA

The letter, sent on 8/4/1978 on behalf of Public Citizen by Sidney M. Wolfe, M.D. and Benjamin Gordon, states: "The strong likelihood that talc is carcinogenic was the subject of a letter from Dr. Marshall E. Deutsch to the New England Journal of Medicine on February 16, 1978. . . If there is good reason to believe – even if the evidence is not conclusive – that talc is carcinogenic, prudence would dictate that its use be eliminated promptly in FDA-regulated products such as drugs and cosmetics."[29]

1979 Dr. Kennedy responds to Citizens Petition letter

On 1/11/1979, Dr. Kennedy replied to Dr. Wolfe and Dr. Gordon: "There is to date no conclusive evidence that pure talc is carcinogenic in man or animals . . . [T]he evidence implicates asbestos contamination of talc as the offending exposure in "talc" carcinogenesis. Meanwhile the FDA Bureau of Foods has carried out several x-ray powder diffraction surveys of the asbestos contamination of cosmetic talc (talcum powders). They found that cosmetic grades of talc are usually free of asbestiform particles. For example, in a 1977 investigation of 46 talc samples, the FDA found only three to contain asbestos (tremolite or anthophyllite. . .and even then the level was only 0.1 percent or less. One firm, Johnson & Johnson, has also done extensive testing for asbestiform particles in cosmetic-grade talc; all results to date have been negative. . . At present, we believe that if talc poses any risks in the products under our control, it is related to contamination by asbestos fibers. However, the FDA is prepared to take whatever prudent additional action is indicated to protect the public health, if and when results of definitive tests show that the kinds of talc in foods, drugs, or cosmetics may represent a carcinogenic hazard. . . "[30]

1982 Cramer publishes the first epidemiological study linking the genital use of talcum powder with ovarian cancer.

This article "provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas**. . .** If talc is involved in the etiology of ovarian cancer, it is not clear whether this derives from the asbestos content of talc or from the uniqueness of the ovary which might make it susceptible to carcinogenesis from both talc and other particulates."[31]

1982 Letter from Allen R. Halper, Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods, to Raymond J. Russell

"The matter of contamination of talc with fibrous asbestos was extensively studied by both the Food and Drug Administration and industry in the mid to late 1970's. We have

[29] JNJ 000254361
[30] JNJ000000251-254
[31] Cramer 1982

> no knowledge of any cosmetic talc products on the market that contains fibrous asbestos. . . While we understand talc is chemically closely related to asbestos, we believe that the needle-like particles that you have briefly described in your letter are talc needles, not fibrous asbestos."[32]

1983 Petition for labeling of the hazardous effects produced by asbestos in cosmetic talc

> Philippe Douillet filed a petition stating, "[t]he purpose of this petition is to request a labeling of warning as well as a detailed list of components of the commercial cosmetic talcs. Because of its geological formation cosmetic talc may contain significant amounts of asbestos particle producing hazardous effects by its continuous use."[33] FDA denied the petition: "[W]e find that there is no basis at this time for the agency to conclude that there is a health hazard attributable to asbestos in cosmetic talc. Without evidence of such a hazard, the agency concludes that there is no need to require a warning label on cosmetic talc."[34] "An internal memo relating to this petition states: FDA surveillance activities that were conducted I the latter portion of the 1970s showed that the quality of cosmetic talc had significantly improved, and that even when asbestos was present, the levels were so low that no health hazard existed."[35]

1985 QRAC (Quantitative Risk Assessment Committee) Memorandum: Asbestos in Talc

> "For completeness, a discussion is presented on a human epidemiological study purporting to show an association between talc use (talcum powder used for genital dusting on the perineum or on sanitary napkins) and ovarian cancer. The Cramer et al. study, which purported to show a significantly increased relative risk for ovarian cancer associated with talc use, 1) appears to have been misinterpreted statistically, 2) was uncorrected for several likely biasing factors, and 3) appears to have been strongly contradicted by another study showing a reduced relative risk as significant in the negative direction as the Cramer study was in the positive direction [Hartge]. . . In addition, there appears to be no association between customary human talc use per se and ovarian cancer."[36] [Hartge reported estimated relative risk of 2.5 with genital talc use]

1992 Harlow publishes epidemiological study linking the genital use of talcum powder to ovarian cancer.

> "These data support the concept that a lifetime pattern of perineal talc use may increase the risk for epithelial ovarian cancer but is unlikely to be the etiology for the majority of epithelial ovarian cancers."[37]

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[32] 1982.12.3 FOIA Response to Russell on Particles in Talc Baby Powder
[33] JNJTALC000173803, FDA00003595
[34] JNJNL61_000067348
[35] FDA_FOIA_004675-7
[36] JNJ000047066-74
[37] Harlow 1992

1993 NTP publishes Technical Report on the Toxicology and Carcinogenesis Studies of Talc

This was an animal study performed using "non-asbestiform" talc. "Under the conditions of these inhalation studies, there was *some evidence of carcinogenic activity** of talc in male F344/N rats based on an increased incidence of benign or malignant pheochromocytomas of the adrenal gland. There was *clear evidence of carcinogenic activity* of talc in female F344/N rats based on increased incidences of alveolar/bronchiolar adenomas and carcinomas of the lung and benign or malignant pheochromocytomas of the adrenal gland. There was *no evidence of carcinogenic activity* of talc in male or female B6C3Fl mice exposed to *6* or 18 mg/m3."[38]

1994 ISTRP and FDA sponsor Workshop - Talc: Consumer Uses and Health Perspectives[39]

Workshop on 1/31/1994 moderated by Dr. John Bailey, Director of FDA's Office of Cosmetics and Colors. In his introductory remarks, Dr. Bailey commented on two recent studies. Describing the first NTP animal study, he stated, "This study, using cosmetic grade talc reported that under the conditions of the study there was some evidence of carcinogenic activity in male rats. There was clear evidence of carcinogenic activity of talc in female rats, and there was no evidence of carcinogenic activity of talc in male or female mice." Regarding the Harlow observational study, he further stated, "In these epidemiology studies the authors concluded that a lifetime pattern of perineal talc use may increase the risk of epithelial ovarian cancer. The authors went on to note that this use is unlikely, however, to be the etiology for the majority of epithelial ovarian cancer cases."

1994 Public Citizen's Petition Requesting warning on Talcum Powder Products

On 11/23/1994, Dr. Epstein sent, on behalf of Cancer Prevention Coalition, a "citizen petition" requesting that FDA take the following action: "immediately require cosmetic talcum powder products to bear labels with a warning such as "Talcum powder causes cancer in laboratory animals. Frequent talc application in the female genital tract increases the risk of ovarian cancer."[40]

1995 Response to Citizen's Petition

John Bailey wrote to Jill Cashen at Cancer Prevention Coalition to inform her that FDA has "not been able to reach a decision on your petition within the first 180 days of the filing of the petition because of the limited availability of resources and other agency priorities."[41]

[38] National Toxicology Program Technical Report Series No. 421
[39] IMERYS 210472-693
[40] JNJ 000018407-16
[41] BAILEY_0003251

2001 Bain Environmental Study Proposal to Donald C. Harvey, Chief, Cosmetics Technology Branch, Office of Cosmetics and Colors to Determine Composition of Cosmetic Talc

> "The proposed study will examine the composition of cosmetic grade talc, focusing on the presence of asbestos. Asbestos, a known carcinogen, can be found in talc if the mining site is not carefully selected or if the talc ore is not sufficiently purified. The asbestos as a factor in the cause of ovarian cancer. The National Toxicology Program (NTP) is considering talc as a possible compound for restudy. The Cosmetic Ingredient Review (CIR) recently decided to perform a separate review of talc because of the toxicological issues relating to talc use. There are few current data available on cosmetic talc composition. The data collected in this survey will be needed in order for the agency to pursue any regulatory action in the event of adverse findings by the NTP or CIR. The data collected will also assist in addressing the citizen petition's request for a warning label on talc products. Abstract of Research Plan: Epidemiological studies have linked talc use by females in perineal are with ovarian cancer, one of the leading causes of death in American women. Talc and asbestos, a known carcinogen, can be found together if the mining site is not carefully selected or if the talc ore is not sufficiently purified. The asbestos concentration of currently marketed cosmetic talc is needed to clarify the role of asbestos as a factor in the cause of ovarian cancer."[42] It appears that this study was not funded.

2008 Second Petition Seeking a Cancer Warning on Cosmetic Talc Products

> The Petition, filed by Dr. Epstein on behalf of Cancer Prevention Coalition, requests FDA to take the following action: "Immediately require cosmetic talcum powder products to bear labels with a prominent warning such as: "Frequent talc application in the female genital area is responsible for major risks of ovarian cancer."[43]

2009 Personal Care Products Council sends Comments on Citizens Petition to FDA

> In a letter dated July 21, 2009, John Bailey, Executive Vice President PCPC, sent a letter to Division of Dockets Management regarding the Public Citizen Petition. This letter states: Given the lack of evidence of a causal role for talc in ovarian cancer, we therefore respectfully ask that the Petitioners' request for a cancer warning be denied. The basis of the request lacks scientific merit and the addition of a warning label would be inappropriate and unnecessarily alarming.[44]

2009 FDA-PCPC Teleconference 11/4/2009: FDA recognition of CIR findings

> In a summary of this call on 11/4/2009, "Dr. Katz emphasized that she cannot *carte blanche* adopt CIR's findings. That would work only if FDA does the evaluation. For

[42] FDA_FOIA_010269
[43] P-0709
[44] PCPC_MDL00044971-73

now, she doesn't have the manpower, further, the current process does not provide for FDA's review leading to "adopt or not".[45]

2010 IARC Monograph on Talc

Perineal use of talc-based body powder is *possibly carcinogenic to humans (group 2B).* Inhaled talc not containing asbestos or asbestiform fibres is *not classifiable as to its carcinogenicity (Group 3).* (based on literature through 2006)[46]

2010 FDA conducts study on presence of asbestos in talc-containing cosmetic products.

Because FDA's cosmetic laboratories do not have the equipment needed to perform the analyses, FDA searched for a qualified outside laboratory. The study ran from September 28, 2009 to September 27, 2010. The survey found no asbestos fibers or structures in any of the samples of cosmetic-grade raw material talc or cosmetic products containing talc. The results were limited, however, by the fact that only four talc suppliers submitted samples and by the number of products tested. For these reasons, while FDA finds these results informative, they do not prove that most or all talc or talc-containing cosmetic products currently marketed in the United States are likely to be free of asbestos contamination. As Always, when potential public health concerns are raised, we will continue to monitor for new information and take appropriate actions to protect the public health.[47]

2013 Cosmetic Ingredient Review issues Safety Assessment of Talc as Used in Cosmetics

The CIR Expert Panel assessed the safety of talc for use in cosmetics and concluded that it is safe in the present practices of use and concentration; talc is reported to be used at up to 100% in cosmetics. Talc should not be applied to the skin when the epidermal barrier is missing or significantly disrupted. Industry specifications state that cosmetic-grade talc must contain no detectable fibrous, asbestos minerals. Therefore, the large amount of available animal and clinical data the Panel relied on in assessing the safety of talc only included those studies on talc that did not contain asbestos. The Discussion of this safety assessment addressed a number of points that were deliberated.[48]

2014 Response to Citizens Petitions dated 11/17/1994 and 5/13/2008

"FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer."[49]

2016 FDA requests safety information from J&J.

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[45] PCP_ MDL00044971
[46] IARC 2010
[47] IMERYS462959
[48] Safety Assessment of Talc as Used in Cosmetics, Final Report April 12, 2013
[49] 2014 Denial of CPC Citizen Petition

In an email, dated 2/25/2016, Janice Adams-King, Safety Regulatory Safety Project Manager for Office of Drug Evaluation, Division of Nonprescription Drug Products, FDA sends Information Request: "Please provide all safety literature and data regarding talc, including data in support of the safety of this active ingredient and data that shows potential harmful effects for this active ingredient by March 17, 2016."[50]

2016 J&J responds to FDA's Request for Information on Talc

In a letter to Theresa Michele, Jethro Ekuta states the following:

> Please note that talc is inactive, ie, not a pharmacologically active ingredient, and is a major component in many body powders such as Johnson's® Baby Powder and Shower to Shower® Powder, which are classified as cosmetics per regulation. . . Examples of countries that regulate talc in cosmetics include the US, EU, China, Canada, UK, and Brazil. The US FDA lists talc as Generally Recognized as Safe (GRAS) for use in foods and Generally Recognized as Safe and Effective (GRASE) for drugs. It is also listed as a color additive that may be used in coloring drug products and as a component of colors for use in drugs and cosmetics. Talc used in JJCI body powders meets pharmaceutical specifications as established by the European and US Pharmacopoeia. . . In 1976, specifications were developed for cosmetic talc requiring that no detectable fibrous, asbestos mineral be present. This is important for any consideration of preclinical and epidemiological literature prior to 1976, as the presence of asbestos was not necessarily ascertained. . . At Johnson & Johnson Consumer Inc., our confidence in using talc is based on more than 100 years of safe use and more than 30 years of research by independent researchers, scientific review boards and global regulatory authorities. Various agencies and governmental bodies have examined whether talc is a carcinogen, and none have concluded that it is. The scientific literature, post-market experience, and expert opinion do not support the association of talc and ovarian cancer.[51]

[50] JNJ000523964
[51] JNJ 000489313

SCHEDULE 2: RELEVANT STANDARDS FOR TALC[52]

[52] Not an exhaustive compilation of standards, but simply the most relevant to this litigation.

List of Relevant Regulatory & Standard-Promulgating Bodies:

ASTM – American Society of Testing and Materials
BP – British Pharmacopoeia
EP – European Pharmacopoeia
FDA – Food and Drug Administration
JP – Japanese Pharmacopoeia
KP – Korean Pharmacopoeia
NF – National Formulary
PCPC (formerly CTFA) – Personal Care Products Council (formerly Cosmetic, Toiletry and Fragrance Association)
SFDA – Chinese State Food and Drug Agency
USP – United States Pharmacopeia

1) Regulatory or Standards Publications

- **United States Pharmacopeia-National Formulary (USP-NF)**

The United States Pharmacopeia Convention (USP), a non-governmental organization, publishes two compendia each year, along with various revisions and supplements: The United States Pharmacopeia & The National Formulary (USP-NF). These publications are currently in their 42nd & 37th Editions respectively as of November 1, 2018. https://www.uspnf.com/publication-comment-schedule. The compendia contain monographs on various chemicals, ingredients, and substances used in drugs, medical devices, cosmetics, etc. Included in the USP compendia is a monograph on talc that includes its definition and various testing methods for potential contaminants. The Excipients Monograph 2 Expert Committee is responsible for the Talc Monograph. http://www.usp.org/expert-committees/excipient-monographs-2-expert-committee-work-plan (linked Excel spreadsheet). Over the years, employees from Imerys (previously Luzenac or Rio Tinto), including Jocelyn Ferret and Julie Pier, have held positions on this expert committee. IMERYS 437666; IMERYS 456885. Both were members during what appears to be the most recent revision to the USP test method for the absence of asbestos in the Talc Monograph. IMA-NA0024007.

USP 28 Talc Monograph, 2nd Supplement: IMERYS 442501

- **Food Chemicals Codex (FCC)**

"The Food Chemicals Codex (FCC) [also published by USP] is a compendium of internationally recognized standards for the identity, purity, and quality of food ingredients." https://www.usp.org/frequently-asked-questions/food-chemicals-codex-fcc

The FCC, currently in its 11th edition, includes a monograph on talc.

FCC 7th Ed. Talc Monograph: IMERYS 456885.061-063

- **International Cosmetic Ingredient Dictionary and Handbook**

PCPC, a cosmetic industry trade association and defendant in this litigation, publishes the *International Cosmetic Ingredient Dictionary and Handbook* (previously called the *CTFA Cosmetic Ingredient Dictionary*). This Dictionary provides uniform names and definitions for cosmetic ingredients (INCI, International Nomenclature Cosmetic Ingredient), lists cosmetic ingredient suppliers, and provides other information relevant to ingredients. Since its first publication in 1973, there have been 16 editions published, with the most recent edition in 2016. The FDA currently recognizes cosmetic ingredient names based on the 2nd Edition of the Dictionary (21 CFR 701.3(c)). The sections on specific ingredients are called Monographs (i.e., the Talc Monograph).

CTFA 2d Edition: https://law.resource.org/pub/us/cfr/ibr/003/cfta.cosmetic.1977.pdf

ICID 16th Edition (introduction only, excluding monographs):
http://webdictionary.personalcarecouncil.org/ctfa-static/online/FrontMatter_Vol1%20Edited%20for%20Websites.pdf

- **European Pharmacopoeia (EP)**

Created by the Convention on the Elaboration of a European Pharmacopoeia, the European Pharmacopoeia, developed by the European Pharmacopoeia Commission and currently in its 9th Edition, includes a monograph on talc.
https://www.edqm.eu/en/european-pharmacopoeia-commission
https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-9th-edition

European Pharmacopoeia 7.0: http://www.fptl.ru/biblioteka/farmacop/EP-7.0-2.pdf (Talc Monograph starts on p. 1687)

- **British Pharmacopoeia (BP)**

The British Pharmacopoeia, developed by the British Pharmacopoeia Commission, incorporates monographs from the European Pharmacopoeia and provides additional monographs.
https://www.pharmacopoeia.com/what-is-the-bp
https://www.pharmacopoeia.com/the-bp-Commission

2) Testing Standards & Specifications[53]

- **PCPC/CTFA**

Test/Standard	Name (or Method)
Identification	CTFA G 3-1
Acid-Soluble Substances	CTFA E 32-1
Screen Test	CTFA C 6-1
Loss on Ignition	CTFA E 36-1
Arsenic	CTFA E 1-1, Parts I-a and II
Lead	CTFA E 2-2, Parts I-A and II
Fibrous Amphibole (Asbestiform Tremolite, et al)	CTFA J 4-1
Quartz	CTFA J 5-1 (DTA) or CTFA J 6-1 (XRD)

JNJ000304864 (*CTFA Compendium of Cosmetic Ingredient Composition*, 1990)
JNJ000349424 (specification current as of 2000)

- **USP**

Test/Standard
Identification
Microbial Limits
Acidity and alkalinity
Loss on Ignition
Water-soluble substances
Limit of Iron
Limit of Lead
Limit of Calcium
Limit of Aluminum
Absence of Asbestos
Content of Magnesium

IMERYS 442501

- **ASTM**

ASTM D6620 - 06(2010)
Standard Practice for Asbestos Detection Limit Based on Counts
https://www.astm.org/Standards/D6620.htm

ASTM D5756-02(2008)

[53] Current as well as historical testing methods included. At times, Defendants used internally developed testing methods or other methods not included in this Schedule.

Standard Test Method for Microvacuum Sampling and Indirect Analysis of Dust by Transmission Electron Microscopy for Asbestos Mass Surface Loading (Withdrawn 2017) https://www.astm.org/DATABASE.CART/WITHDRAWN/D5756.htm

- **Comparison of testing standards:**

Global Cosmetic and Pharmacopeia Standards

	USP	EP	JP	KP	CTFA	China P
Loss on ignition	7% (1050-1100 C)	7% 1(050-1100 C)	5.0% (450-550°C, 3	5.0% (450-550°C, 3 hours)	6%	17.0% (800°C)
Water soluble substances	0.10%	0.20%	4.0 mg	4.0 mg	0.10%	-
Acid soluble substances			2.0%	2.0%	6%	
Arsenic			4 ppm	4 ppm	3 ppm	0.0002%
Iron	0.25%	0.25%	Compliant	0.25%	0.25%	-
Lead	10 ppm	10 ppm	20 ppm	0.001%	20 ppm	15 ppm
Aluminum	2%	2%	-	2.0%		yes
Magnesium	17-19.5%	17-19.5 %	-			yes
Calcium	0.90%	0.90%	-	0.9%		-
Asbestos	Non-detect: IR/XRD...PLM	Non-detect: IR/XRD...PLM	-	Non-detect: IR/XRD...PLM	Non-detect: Method J4-1 XRD...PLM	Standard in progress

IMERYS 444294 (2011)

- **Published Specifications as of 2004 (IMERYS 418301-02)**

Organization	Specification	Remarks
ACGIH	Talc containing no asbestos fibers – TLV-TWA, 2 mg/m^3, Respirable particulate fraction. ********** Talc containing asbestos fibers – TLV-TWA, Use asbestos TLV; however, should not exceed 2 mg/m^3, respirable particulate fraction	A4 – Not Classifiable as a Human Carcinogen "Evidence is ample that the dust or particulate of non-fibrous talc, consisting almost entirely of platiform talc crystals and containing no asbestos, carries a relatively small respiratory hazard for exposed workers." ********** A1 –Confirmed Human Carcinogen.
NIOSH	Talc (containing no asbestos and less than 1% quartz) - TWA 2 mg/m^3 (respirable dust)	Symptoms: Fibrotic pneumoconiosis; irritation eyes
OSHA	TABLE Z-1 LIMITS FOR AIR CONTAMINANTS Talc (containing asbestos): use asbestos limit: see 29 CFR 1910.1001 Talc (containing no asbestos), respirable dust: see Table Z-3 ********** TABLE Z-3 MINERAL DUSTS Talc (not containing asbestos): 20 mppcf Talc (containing asbestos) Use asbestos limit.	It should be noted that OSHA proposed adopting the ACGIH TLV of 2mg/m^3 in the1989 Final Rule on Air Contaminants (54FR2332 et. seq.). The U.S. Circuit Court of Appeals remanded this rule and the limits are not currently in force.
IARC	Talc not containing asbestiform fibres is not classifiable as to its carcinogenicity to humans (Group 3). ********** Talc containing asbestiform fibres is carcinogenic to humans (Group 1).	
CTFA	Specification: Fibrous Amphibole (Asbestiform Tremolite et al) – "None detected"	Talc Definition: "Talc is…and containing no detectable fibrous, asbestos minerals."
FCC	Talc derived from deposits that are known to contain associated asbestiform minerals is not food grade.	
Prop 65	CHEMICALS KNOWN TO THE STATE TO CAUSE CANCER OR REPRODUCTIVE TOXICITY: Talc containing asbestiform fibers	Listed April 1, 1990

IPCS	Talc (Silica and Fibre Free) – TLV: 2 mg/m^3 as TWA	The substance may have effects on the lungs, resulting in talc pneumoconiosis.
ILO	Talc (Silica and Fibre Free) – TLV: 2 mg/m^3 as TWA	The substance may have effects on the lungs, resulting in talc pneumoconiosis.
WHO IPCS ILO	Talc (Silica and Fibre Free) – TLV: 2 mg/m^3 as TWA	The substance may have effects on the lungs, resulting in talc pneumoconiosis.

3) Government Regulations Directly Applicable to Talc

21 CFR 73.1550

PART 73 -- LISTING OF COLOR ADDITIVES EXEMPT FROM CERTIFICATION

Subpart B--Drugs

Sec. 73.1550 Talc.

(a) Identity. (1) The color additive talc is a finely powdered, native, hydrous magnesium silicate sometimes containing a small proportion of aluminum silicate.

(2) Color additive mixtures for drug use made with talc may contain only those diluents listed in this subpart as safe and suitable for use in color additive mixtures for coloring drugs.

(b) Specifications. Talc shall meet the specifications for talc in the United States Pharmacopeia XX (1980) and the following:

Lead (as Pb), not more than 20 parts per million.

Arsenic (as As), not more than 3 parts per million.

Lead and arsenic shall be determined in the solution obtained by boiling 10 grams of the talc for 15 minutes in 50 milliliters of 0.5N hydrochloric acid.

(c) Uses and restrictions. Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally.

(d) Labeling requirements. The label of the color additive and of any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of 70.25 of this chapter.

(e) Exemption from certification. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements of section 721(c) of the act.

21 CFR 182.2437

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart C--Anticaking Agents

Sec. 182.2437 Magnesium silicate.

(a) Product. Magnesium silicate.

(b) Tolerance. 2 percent.

(c) Limitations, restrictions, or explanation. This substance is generally recognized as safe when used in table salt in accordance with good manufacturing practice.

21 CFR 178.3297

PART 178 -- INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

Subpart D--Certain Adjuvants and Production Aids

Sec. 178.3297 Colorants for polymers.
The substances listed in paragraph (e) of this section may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions and definitions set forth in this section:

(a) The term colorant means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term "colorant" includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5001 Campus Dr., College Park, MD 20740, 240-402-1200

(d) Color additives and their lakes listed for direct use in foods, under the provisions of the color additive regulations in parts 73, 74, 81, and 82 of this chapter, may also be used as colorants for food-contact polymers.

(e) List of substances:

. . .

Magnesium silicate (talc)

. . .

21 CFR 176.170

PART 176 -- INDIRECT FOOD ADDITIVES: PAPER AND PAPERBOARD COMPONENTS

Subpart B--Substances for Use Only as Components of Paper and Paperboard

Sec. 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.
Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packaging, processing, preparing, treating, packing, transporting, or holding aqueous and fatty foods, subject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of table 1 in paragraph (c) of this section are subject to the provisions of 176.180.

(a) Substances identified in paragraph (a) (1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: Provided, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: And provided further, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be available from manufacturing records from which it is possible to determine that only substances identified in this paragraph (a) are present in the food-contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

. . .

Magnesium silicate (talc) Do.

. . .

21 CFR 182.70

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A--General Provisions

Sec. 182.70 Substances migrating from cotton and cotton fabrics used in dry food packaging.

Substances migrating to food from cotton and cotton fabrics used in dry food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

. . .

Talc.

. . .

21 CFR 182.90

PART 182 -- SUBSTANCES GENERALLY RECOGNIZED AS SAFE

Subpart A--General Provisions

Sec. 182.90 Substances migrating to food from paper and paperboard products. Substances migrating to food from paper and paperboard products used in food packaging that are generally recognized as safe for their intended use, within the meaning of section 409 of the Act, are as follows:

. . .

Talc.

. . .

21 CFR 310.545

PART 310 -- NEW DRUGS

Subpart E--Requirements for Specific New Drugs or Devices

Sec. 310.545 Drug products containing certain active ingredients offered over-the-counter (OTC) for certain uses.

(a) A number of active ingredients have been present in OTC drug products for various uses, as described below. However, based on evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of these ingredients for the specified uses:

. . .

(18) Skin protectant drug products --(i)(A) Ingredients--Approved as of May 7, 1991.

. . .

(B) Ingredients--Approved as of June 4, 2004; June 6, 2005, for products with annual sales less than $25,000.

. . .

(ii) Astringent drug products.

. . .

Talc

. . .

55 F.R. 25224 (June 20, 1990)

In the comments on talc for proposed rulemaking amending the tentative final monograph for over-the-counter (OTC) skin protectant drug products, the FDA noted that “Cosmetic talc should contain at least 90 percent platy talc (having flat as opposed to fibrous particles) that is free of detectable amounts of fibrous minerals, including asbestos.”

SCHEDULE 3: EXAMPLES OF TALC IN FDA REGULATED PRODUCTS

Food	21 CFR 178.3297	Magnesium silicate (talc) may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, transporting, or holding food.
	21 CFR 182.2437	Magnesium silicate is generally recognized as safe when used in table salt in accordance with good manufacturing practice.
	21 CFR 182.70	Talc migrating to food from cotton and cotton fabrics used in dry food packaging are generally recognized as safe.
	21 CFR 182.90	Talc migrating to food from paper and paperboard products used in food packaging are generally recognized as safe.
Drugs	21 CFR 73.1550	Talc may be safely used in amounts consistent with good manufacturing practice to color drugs generally. Certification of this color additive is not necessary for the protection of the public health, and therefore batches thereof are exempt from the certification requirements. Talc must still meet USP specifications for talc.
	21 CFR 310.545	Based on the evidence currently available, there are inadequate data to establish general recognition of the safety and effectiveness of talc in astringent drug products for skin protectant drug products.
	Transcript from FDA Joint Meeting of the Anesthetic and Analgesic Drug Products and Drug Safety and Risk Management Advisory Committees	Some opioids contain talc as an excipient and contain labeling due to its presence that "parenteral abuse can be expected to result in local tissue necrosis, infection, pulmonary granulomas."
	FDA presentation at a Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee and the Drug Safety and Risk Management Advisory Committee	In the discussion on labeling, they note, "due to the presence of talc as one of the excipients in MS CONTIN, parenteral abuse can be expected to result in local tissue necrosis, infection, pulmonary granulomas, and increased risk of endocarditis and valvular heart injury."
Medical Devices	21 CFR 895.102	Powdered surgeon's gloves are banned medical devices
	21 CFR 895.103	Powdered patient examination gloves are banned medical devices
	21 CFR 895.104	Absorbable powder for lubricating a surgeon's glove are banned medical devices

SCHEDULE 4: EPIDEMIOLOGICAL LITERATURE TABLE

I. COHORT STUDIES

AUTHOR	STUDY DESCRIPTION	FINDINGS	LIMITATIONS	DISCUSSION AND CONCLUSIONS
Gertig (2000) Gates (2008) Gates (2010)	Cohort Study (Nurses' Health Study "NHS") Study of 121,700 registered nurses between ages 30-55 years from across US. Talc use determined by self-administered 1982 questionnaire. Asked women if they had ever commonly used talcum, baby powder, or deodorizing powder on their perineal. Possible responses were: no, daily, 1-6 times per week, or < 1/week. Also asked if they had applied products to sanitary napkins. "Ever talc use" classified as ever talc use on either perineal area or sanitary napkins. Every two years, participants reported health updates; no updates on talc use were included, but self-reported cases of ovarian cancer were adjudicated through medical record reviews. Exclusions for incomplete questionnaires on talc, if reported both ovaries removed, if reported a hysterectomy but did not report whether at least one ovary remaining, or history of radiation therapy. Three publications resulted from this study. The first, published in 2000, included 78,630 women, of whom 307 cases of ovarian cancer were diagnosed. Ever use of talc was reported by 40.4% of the cohort; 14.5% ever used talc daily.	**2000 (1st Report):** •Ever Talc Use – R.R. 1.09 (0.86 – 1.37) •Invasive Serous Ovarian Cancer – R.R. 1.40 (1.02 – 1.91) **Gates 2008 Follow-up (2nd):** •Epithelial OC = 1.36 (1.14 – 1.63) •Serous OC = 1.60 (1.26 – 2.02) **Gates 2010 Follow-up (3rd):** •Results not statistically significant for talc exposure •All epithelial = 1.06 (0.89 – 1.28) •Serous = 1.06 (0.84 – 1.35)	**OVERALL** The questions on talcum powder use referred to ever use and cannot determine the age at which women began using talc or the duration. Relatively short follow-up. Tubal ligation questions asked as part of contraception. **2010 (2nd Follow-up)** • Extended the follow up through 2006 but no updated use or exposure data	**2000:** Prospective Study No overall association between "ever use" of talcum powder and total risk for ovarian cancer (R.R. 1.09; 95% CI .86 – 1.37) 40% Increased risk for serous invasive cancer with any (ever) history of talc use which comprises the majority of ovarian cancer (R.R. 1.40; 95% CI 1.02 -1.9) Risk stratified by histologic sub-type There was no apparent dose response, although lacked information on duration of use. **2008:** •Regular talc use was associated with increased ovarian cancer risk in the combined study population (RR, 1.36; 95% CI, 1.14-1.63; Ptrend < 0.001). may have a higher risk of ovarian cancer associated with genital talc use. These results provided additional support for a main effect of genital talc exposure on risk of epithelial ovarian cancer. The presence of a significant trend between frequency of talc use and risk of total and serous invasive ovarian cancer in the NECC and pooled analysis further strengthens the evidence for an association, as most previous studies have not observed a dose-response

	The second report from the Nurses' Health Study was in 2008. This was a pooled analysis post-NHS: 2 phases (1992-1997; 1998-2003). Results from the Nurses' Health Study were combined with other cases and controls from case-control studies. Study updated talc analysis from NHS, including 8 additional years of follow-up. Analysis included 1,175 cases and 1,202 controls from a New England-based case-control study and 210 cases and 600 controls from the prospective Nurses' Health Study. •Additional support for the presence of a significant trend between the frequency of talc use and risk of total and serous ovarian cancer The third Nurses' Health Study report was published in 2010. This analysis included women from two separate cohorts; the exact numbers of women and cases with exposure data regarding talc was not specified.			with increasing frequency or duration of talc use. Inflammatory response in vivo In vitro study where cells undergo cell proliferation, neoplastic transformation and cellular generation of reactive oxygen species increasing with increased exposure to talc Although no prior studies have examined gene-talc interactions, the indication of a possible immune-related mechanism between talc and ovarian carcinogenesis and the evidence for gene-asbestos interactions suggest that genes involved in detoxification and inflammatory pathways could be important in the response to talc. **2010** The incomplete data for a few exposures, in particular talc use and family history of ovarian cancer, also are weaknesses because the limited data may have influenced the observed associations for these exposures. The association with talc use in our analysis differed from the association in a previous analysis of the NHS cohort (34), possibly because of a greater degree of exposure misclassification over 24 years of followup. However, the suggestive positive association with the mucinous subtype may reflect a longer latency period

				between talc exposure and development of mucinous tumors. Finally, the use of a single summary measure for certain exposures, such as physical activity, also may have limited our ability to detect an association. Associations differ by subtype.
Houghton (2014)	Cohort Study (Womens Health Initiative) • Enrolled 93,676 women between 1993-1998 • 61,576 post-menopausal participants in the study cohort • 429 total ovarian cancer cases • Average age at time completed questionnaire of talc use 62-63.3 • Follow up for disease ascertainment was a mean of 12.4 years • Included post-menopausal women between 50 & 79 • Talc use assessed at baseline with self-reporting questionnaires	• Use of genital powders for >20 years resulted in a RR 1.06, 95% CI (0.87-1.28) • Risk of serous invasive cancer was increased by a non-statistically significant 13% (hazard ratio 1.13, 95% CI 0.84 - 1.51).	Asked about duration of use only. The study may have been comparing long-term infrequent users with short term frequent users. Lack of information regarding oophorectomy after baseline Non-differential misclassification (need to recall past use and duration); leading to a bias toward the null Information on use was not collected after baseline. Assumed women remained in same exposure group for 12 years Information of powder use not collected after baseline Short follow-up period (12.4 years) Obtained information on duration of use via interviews, but unknown during which years powder used (i.e. application on genital area, sanitary napkins and diaphragm) Queried general powder use rather than talc powder and had no specific information	Ever perineal powder use was not associated with ovarian cancer risk, nor was it associated with ovarian cancer when assess by area of application, duration of use, or ovarian cancer subtype.

			regarding the content of talc in products used.	
Gonzalez (2016)	Cohort Study (Sister Study) The Sister Study, launched in 2003, enrolled 50,884 women who had a sister diagnosed with breast cancer Participants included 154 exposed cases with ovarian cancer who did not have diagnosis of breast cancer but sister had breast cancer Enrollees were ages 35-74 years At baseline, participants asked about talc and douching use during the previous 12 months 52% menopausal	•Talc - H.R. 0.73 (0.44 – 1.2) •Douching – O.R. 2.1 (2.0 – 2.3)	Not a talc or ovarian cancer study Baseline questionnaire inquired of douching and talc use during the previous 12 months of study initiation Questionnaire did not inquire about lifetime exposures 37% of cases had no medical records 84% white women; 56% post-menopausal Short follow-up 6.6 years Reported prevalence of talc use was 14%.	Douching, not talc use, associated with increased risk of ovarian cancer

II. CASE CONTROL STUDIES

AUTHOR	STUDY DESCRIPTION	FINDINGS	REPORTED LIMITATIONS	AUTHORS' DISCUSSION AND CONCLUSIONS
Cramer (1982)	Case Control Study. Population based. Evaluated 215 women with epithelial ovarian cancer and 215 age-matched control from greater Boston, MA area. Talc exposure was determined by questionnaire regarding "regular" talc use on the perineum and/or on sanitary napkins. 42.8% of ovarian cancer patients reported regular use of talc (prior to developing	*Adjusted for parity and menopausal status, any perineal talc exposure reported a relative risk of 1.92 (1.27-2.89) for epithelial ovarian cancer. Women who had regularly engaged in both perineal use and on sanitary napkins had an adjusted relative risk of 3.28 (1.68-6.42) compared to women with neither exposure.*	Potential biases include that menstrual characteristics may differ between women with ovarian cancer and controls. Further since talc into the pelvic cavity is prevented by hysterectomy or tubal ligation inclusion of subjects with pelvic surgery may obviate any association between talc and ovarian cancer. Other confounders include potential for selection bias. Etiology may derive from asbestos content of talc	The argument linking talc and ovarian cancer includes four elements: the chemical relationship between talc and asbestos, asbestos as a cause of pleural and peritoneal mesotheliomas, the possible relation between epithelial ovarian cancers and mesotheliomas, and the ability of talc to enter the pelvic cavity. The mineral talc is a specific hydrous magnesium silicate chemically related to several asbestos group minerals and

	ovarian cancer) compared to 28.4% of controls.		or uniqueness of the ovary which make it susceptible to carcinogenesis from both talc and other particulates. Recall bias is also a potential limitation.	occurring in nature with them. Generic "talc" is seldom pure and may be contaminated with asbestos, particularly in powders formulated prior to 1976. This study provides some support for an association between talc and ovarian cancer hypothesized because of the similarity of ovarian cancer to mesotheliomas and the chemical relation of talc to asbestos, a known cause of mesotheliomas.
Hartge (1983) (Letter to the Editor)	Case Control Study. Hospital based. Evaluated 135 women with epithelial ovarian cancer and 171 controls from the Washington, DC area. Talc exposure was ascertained via questionnaire, but the authors did not provide detail as to questions asked.	The authors reported that women who reported any talc use (body powder or diaphragm) had an estimated relative risk of **0.7 (0.4-1.1)**, while use on their genitals had an estimated relative risk of **2.5 (0.70-10.0)** compared with never users.	The analysis was based on only 7 cases and 3 controls. Chance, bias in selection or observation, or confounding may have influenced these estimates. Further, patients with ovarian cancer may have or perceived a greater need for using body powder in the genital area for reasons related to their ovarian cancer or life style.	Data indicate no overall association between all talc use and risk of ovarian cancer. Although a small group of women who specifically reported genital use of body talcum powders showed an excess relative risk, use of talc on a diaphragm, which would be closest to the ovaries, did not seem to elevate risk.
Whittemore (1988)	Case Control Study. Hospital based. Evaluation included 188 ovarian cancer cases and 539 controls in the San Francisco, CA area. *Exposure to talc was determined through structured personal interviews and documented type of use including, perineum, sanitary pads, diaphragm or some combination of these uses. Duration of talc use was also ascertained.*	Women who reported using talcum powder to the perineum showed a relative risk of **1.45 (0.81-2.60).** Use on sanitary pad was associated with a non-statistically significant 38% reduce risk and use on diaphragms was associated with a non-statistically significant 50% increased risk. The relative risk for ovarian cancer increased with increasing applications of talc per month; relative to nonusers, the relative risk for 1-20 times per month was **1.27**, and the relative risk for 20 or more times per month was **1.45**. None of these values was	The study results should be interpreted cautiously based on the studies' failure to interview all eligible controls, potential pitfalls in combining two studies and the two control groups in the second study. The is also the possibility of confounding by unmeasured variables.	The data show a trend of increasing risk with increasing frequency of perineal talc exposure, but the trend was not statistically significant. Thus, while these data do not exonerate talc as an ovarian carcinogen, neither do they provide strong evidence to implicate it.

		statistically significant. The increased relative risk was apparent for women who had never had tubal ligation or hysterectomy, but not for women who had had one of these procedures. Compared with non-users, women with 1-9 years of use had a relative risk of **1.6 (1.00-2.57),** but women with greater years of use had only a relative risk of **1.11 (0.74-1.65).**		
Booth (1989)	Case Control Study. Hospital based. Evaluated 235 cases with ovarian cancer and 451 controls in the UK. A questionnaire ascertained the frequency of exposure to talc in the genital area (never, rarely, monthly, weekly, daily).	The authors reported women who used talc in the genital area had the following relative risk for ovarian cancer based on the frequency of exposure: Rarely use: **0.9 (0.3-2.4)** Monthly: **0.7 (0.3-1.8)** Weekly: **2.0 (1.3-3.4)** Daily: **1.3 (0.8-1.9)** Cases and controls did not differ by percentage who kept diaphragms in talc.	As the design is case control there may have been some misclassification of controls. The women were not asked how long they had been using talc (duration).	The evidence linking talc with ovarian cancer is controversial. In this study, women who reported talc use in the genital area more than once a week or daily had higher risks of ovarian cancer than women who used talc less frequently. The women were not asked how long they used talc. It is possible that because of their symptoms talc use by the cases may not have reflected their frequency of past use. Since these and other results (Cramer 1982; Hartge 1983) are insufficient to reject an association, further work is need on the relation between genital use of talc and ovarian cancer.
Harlow (1989)	Case Control Study. Population based. Evaluated 116 women with serous or mucinous borderline ovarian cancer identified through a Western Washington population-based cancer registry, as well a population-based sample of 158 control women. The study used an open-ended	Women who used deodorizing powders had a relative risk of **2.8 (1.1-11.7)** for borderline ovarian tumors, while any perineal exposure to powder showed a relative risk of **1.1 (0.7-2.1)** No data were presented regarding frequency or duration of talc/powder use.	The elevated risk among women who specifically used deodorizing powders could have been due to chance or applicable only to borderline, not malignant ovarian tumors.	Given the clues provided by this study regarding the possible importance of deodorizing powders, it would be advisable for future studies to elicit information on brand name of talc-containing powders and the timing and duration of such use. Although these data need replication, they raise the possibility that the risk of ovarian tumors in women who apply deodorizing powder to the perineum may not relate to talc per se but rather

	question asking women to specify the types of powder they used for perineal application after bathing, on sanitary napkins, and for diaphragm storage. Powder was categorized as baby powder, deodorizing powder, other/unspecified talcum/dusting powders or as cornstarch.			to asbestos contamination and/or a substance or substance used specifically for deodorization. An association between talc use and ovarian neoplasms seems biologically plausible, since particulates contaminating the vaginal area may migrate into the pelvic cavity and since particles of talc have been observed within ovarian tissue.
Chen (1992)	Case Control Study. Population based. Interviewed 112 women with ovarian cancer and 224 community controls in Beijing, China. A questionnaire was developed to obtain histories and data was collected via face-to-face interviews. No information was provided about how women were asked about talc-containing dusting powder product use prior to 3 years before diagnosis (for cases) and a comparable date in controls.	Seven cases and 5 controls reported using "dusting powder" to the lower abdomen and perineum for 3 or more months. After adjusting for education and parity, the users of "talc-containing" dusting powder showed a relative risk of **3.9 (0.9-10.6).**	Given the nature of the cancer registry in China, some of the ovarian cancer patients may not have been ascertained for study. Also, potentially damaging were the high rate of loss due to deaths. A third limitation was the exclusion of controls with current health problems. The small number of subjects of exposed to talc is another limitation.	Similar to previous studies, a threefold increased risk was associated with perineal talc exposure. It is interesting that that similar results are obtained from quite different parts of the world.
Harlow & Cramer (1992)	Case Control Study. Population based. Interviewed *235 white women diagnosed with ovarian cancer in the Boston, MA metropolitan area. Tumors were confirmed through an independent pathology review. Talc exposure was*	*Perineal talc use was associated with an odds ratio for epithelial ovarian cancer of 1.5 (1.0-2.1) when adjusted for parity, education, marital status, religion, use of sanitary napkins, douching, age, and weight. Direct perineal application showed an odds ratio of 1.7 (1.1-2.7). Use of talc on a daily basis increased the odds ratio for*	Authors stated that this study failed to answer a key issue in talc-ovarian cancer association: whether the risk pertains to all cosmetic talc or only to certain preparations likely to be contaminated with asbestos.	Because the overall association between genital use of talc and ovarian cancer remains weak, it is unlikely that this exposure-disease pathway is the principal one involved in ovarian cancer etiology. The authors concluded that they calculate that by applying these odds ratios to the exposure rate among cases, the proportion of ovarian cancer incidence

	determined through in-person interviews. Talc use was reported as any genital application, type of application (sanitary napkin/underwear, via partner or application to diaphragm, via dusting to perineum), number of applications per month, years of use, age at first use, years since last use, whether use was before or after 1960, brand of application, estimated total lifetime applications, estimated applications excluding use after hysterectomy or tubal ligation, and estimated applications excluding use after hysterectomy or tubal ligation and use during nonovulatory months.	*ovarian cancer to 1.8 (1.1-3.0) and use for more than 10 years 1.6 (1.0-2.7). For women who had more than 10,000 applications while menstruating had an odds ratio of 2.8 (1.4-5.4).* *Using techniques of metaanalysis, the authors calculated an OR of 1.3 (1.1-1.6) for any perineal exposure and ovarian cancer risk.*	The variation in risk among histologic subtypes may reflect a chance finding or a need to examine endometroid and borderline tumors more carefully for evidence of foreign body effect. Authors cannot rule out the possibility of differential over or under reporting of talc exposure their cases and controls, especially in those with reproductive events that enhance ORs. Authors presume that responders and non-responders were similar in characteristics, but validity depends on that presumption. Adjustments were made to account for confounding, but authors cannot rule out the presence of unknown factors might have influenced the observed associations.	attributable to this level of talc exposure is about 10%. They further state that given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For that reason, they discouraged the use of talc in genital hygiene, particularly as a daily habit.
Rosenblatt (1992)	Case Control Study. Hospital based. Evaluated a total of 77 cases of ovarian cancer and 46 controls, who were treated for non-gynecologic/non-malignant diseases from Baltimore, MD. Participants were interviewed via questionnaire (questions provided in Appendix 1 of	Women who were exposed to genital fibers greater than or equal to 37.4 years had an increased odds ratio for ovarian cancer of **2.4 (1.0-5.8).** Exposure to talc on sanitary napkins resulted in an increase odds ratio of **4.8 (1.3-17.8).** Use of genital bath talc was associated with an odds ratio of **1.7 (0.7-3.9).** Diaphragm use with powder showed an odds ratio of **3.0 (0.8-10.8).**	Given its small sample size and the potential selection bias stemming from the inclusion of patients from only one hospital, further research needs to be performed in order to confirm the findings.	The authors stated that the results of their study and others suggested that genital fiber exposure may be associated with an adverse effect, but further study is needed to determine if this relationship is causal in nature. Tubal ligation may protect against ovarian cancer by inhibiting carcinogenic action of talc through blockage of the fallopian tube or through screening effect.

	publication) about presence and length of genital fiber and respiratory fiber exposure. Fiber exposure was defined as exposure to asbestos, talc, and fiberglass. The "dose" of exposure was determined by adding the number of years of each type of genital or respiratory exposures from all sources. Further, only exposure prior to tubal ligation (for women who had that procedure) was counted.	A negative association was observed for antecedent tubal ligation with an odds ratio of **0.15 (0.027-0.88).**		
Tzonou (1993)	Case Control Study. Hospital based. Evaluated189 women with ovarian cancer and 200 controls in Greater Athens, Greece area. Exposure was ascertained by asking if women used of talc in the perineal area (no; yes).	After adjusting for variable, talc application in the perineum was associated with a relative risk of **1.05 (0.28-3.98)** based on 6 cases and 7 controls reported using talc in the perineal area.	The study has the power limitation associated with its moderate size and, as in any case-control study, there exists a possibility of selection and, less likely, of information bias. The possibility that ovarian cancer may be caused by exposure to asbestos has be raised by other authors who pointed out that mineral talc is closely related asbestos and presented clinical and experiments evidence linking exposure to talc with ovarian cancer.	The results of the present study do not support an association between talc and ovarian cancer but, given the overlapping range of the confidence intervals, they are not incompatible with it.
Purdie (1995)	Case Control Study. Population based. *Evaluated 824 cases of epithelial ovarian cancer and 860 controls from*	*Use of talc around abdomen/perineum was associated increase risk for ovarian cancer with an odds ratio of 1.27 (1.04 - 1.54).*	Selection and recall biases and potential confounders were considered.	Regular use of talc in the region of the abdomen or perineum was associated with a slight increase (and positively associated) in the risk of ovarian cancer.

	gynecological oncology treatment centers in three Australian states. Talc exposure was determined through use of a questionnaire via face-to-face interviews.			
Cramer (1995)	Case Control Study. Population based. Evaluated 450 women diagnosed with ovarian cancer in Boston, MA area hospitals, and 454 controls selected from the general population. Examined the association between ovarian cancer and prior hysterectomy or tubal ligation.	Use of talc "in genital hygiene" was associated with an increased risk for ovarian cancer with an odds ratio **1.6 (1.2-2.1).**	Authors considered recall bias and confounding	Authors reported a protective effect of prior hysterectomy or tubal ligation for ovarian cancer and offer several explanations including blockage of vaginal contaminants. Thus tubal effluences or vaginal contaminants are no longer able to reach the pelvic cavity and ovaries. Although many vaginal contaminants could be proposed, talc use in genital hygiene may be an important one.
Chang (1997)	Case Control Study. Population based. Evaluated 450 patients with borderline or invasive ovarian cancer and 564 population controls in Ontario, Canada. A questionnaire was used during an in-person interview. Questions about regular talc use and type of talc use, as well as questions from which information about duration and frequency of exposure were included. Women were questioned about the application of talc to the perineum and about use of talc on sanitary napkins.	Women with any regular talc exposure had an increased risk of developing ovarian cancer with an odds ratio of **1.42 (1.08-1.86).** Use of cornstarch was not associated with increased risk, but there were small numbers in this exposure group. Use of talc on sanitary napkins was associated with an odds ratio of **1.26 (0.81-1.96**), and use of talc after bathing showed an odds ratio of **1.31 (1.00-1.73**). Dose response data revealed an odds ratio per 10 years of use at **1.06 (0.99-1.14).**	Differences in talc concentration among various baby powders, body powders and deodorizing powders were not investigated in this study. Furthermore, reporting error in reported talc use and failure to interview all eligible case and control subjects may have led to biases. As with any case control study, the possibility of selection bias and information bias exists, although the consistency of this study with others that have addressed reproductive factors and ovarian carcinoma is reassuring.	This investigation supports previous contentions that exposure to talc may increase risk of ovarian carcinoma. Dusting with talcum powder is not an unusual practice for women and, given the heterogeneity of the etiology and course of ovarian carcinoma, any possible harmful practices, particularly those with little benefit, should be deliberated. A questionable dose-response relationship was observed between duration or frequency of exposure and risk.

	They also ascertained the use of cornstarch on the perineum and sanitary napkins.			
Green (1997)	Case Control Study. Population based. Included 824 women with ovarian cancer who were identified through cancer registries and 855 population-based controls from 3 Australian states. A Questionnaire was used to determine perineal talc exposure but no details were provided on the specific questions posed regarding talc use. Duration and particular ages/years used were also obtained.	Women who had ever used talc in the perineal region had an increased risk for ovarian cancer with a relative risk **1.3 (1.1-1.6).** Further the authors found that compared with women who had neither used talc nor had surgical sterilization, risk was highest among talc users without surgery with a relative risk **1.3 (1.0-1.7)** and lowest among women with a history or tubal sterilization or hysterectomy who had not applied talc to the perineum with a relative risk **0.6 (0.5-0.84).**	Recall of use of talc among older women may not have been accurate, tending to reduce the estimated RRs; moreover, the actual quantity of talc used was unknown.	Despite the limitation, these results add support to the body of evidence implicating talc as a factor in the pathogenesis of peritoneal epithelial neoplasia. Our findings support the theory that contaminants from the vagina, such as talc,… gain access to the peritoneal cavity through patent fallopian tubes and may enhance malignant transformation of the ovarian surface epithelium. Surgical tubal occlusion may reduce the risk of ovarian cancer by preventing the access of such agents. In view of this particular finding (reduction of risk of ovarian and peritoneal tumors) and the evidence presented here and elsewhere that pelvic contaminants such as talc are associated with ovarian cancer, we conclude that closure of the fallopian tubes by surgery prevents chronic contact between these agents and ovarian epithelium. It seem likely that peritoneal irritants act as co-carcinogens by increasing the accumulated number of mutational events in ovarian surface epithelial cells.
Cook (1997)	Case Control Study. Population based. Evaluated 313 cases of ovarian cancer identified through a cancer registry	Use of any of the genital powder applications (perineal application, sanitary napkins, genital deodorant sprays, diaphragms resulted in a relative risk **1.5 (1.1-2.0).** The risk	Study reported that it is difficult to postulate that an increased risk for ovarian cancer may specifically be due to powder and associated	These results offer support for the hypothesis, raised by prior epidemiologic studies, that powder exposure from perineal dusting

	and 422 population-based controls in Western Washington. Women were questioned about storing diaphragms in powder, dusting perineal areas with powder after bathing, powdering sanitary napkins, and using genital deodorant sprays. Women were also questioned about duration and frequency of powder application and about types of powder applied.	was highest in women who dusted perineal areas with powder, with a relative risk **1.8 (1.2-2.9).** Compared with never users of genital deodorant sprays, women who used these products for 12 months or less had a relative risk for ovarian cancer of **1.5**, while those who used them for more than 12 months had a relative risk of **2.7**. Compared with never users of genital deodorant sprays, women who used an estimated 500 lifetime applications or less of genital deodorant sprays had a relative risk for ovarian cancer of **1.7**, while those who had an estimated lifetime applications greater than 500 had a relative risk of **2.6.** Both of these dose-response trends were statistically significant ($p < 0.05$). None of the other types of perineal talcum powder product use showed trends to greater risk with greater estimated duration used or applications. The authors then categorized powders into specific types: cornstarch, talcum powder, baby powder, deodorant powder, and scented body/bath powder (assuming talcum powder was likely a constituent of the latter three as well). Exclusive use of cornstarch only or of deodorizing powder only were associated with no increase in risk for ovarian cancer, but the numbers of cases were very small (5 and 9, respectively). Exclusive use of other types of powder increased risk between 20 and 60 percent, but the results were not statistically	constituents when some of the deodorant sprays do not contain aerosolized powder. Limitations of the present study include the fairly low proportion of eligible women who participated and the potential differential recall of powder usage.	contributes to the development of ovarian cancer. Given the common practice (28-51% of women), even the modest elevation in ovarian cancer risk by most epidemiological studies could have a notable impact on the incidence of ovarian cancer in the US.

		significant. Risk for serous ovarian cancers increased in women who ever used any genital powder with a relative risk **1.7 (1.1-2.5).** The relative risk for "other tumors" among ever users was **1.8 (1.1-2.8),** while risks for mucinous or endometrioid tumors were not increased in genital powder users.		
Godard (1998)	Case Control Study. Population based. Evaluated 170 women with ovarian carcinomas or borderline tumors and 170 controls in Montreal, Canada. The authors used questionnaires, but talc use questions were not described in the publication. However, the variable of "ever" versus "never" perineal use of talc was reported.	Women who had ever used perineal talc had an increased risk for ovarian cancer with a relative risk **2.49 (0.94-6.58).** The relative risk for sporadic ovarian cancer **2.45 (0.85-7.07),** and a relative risk of **3.25 (0.85-12.4)** for familial ovarian cancer.		Perineal talc used was a nonsignificant risk factor (RR 2.49, P=.064). Talc has previously been implicated in the development of ovarian cancer. Although there are reports of talc embedded in human ovarian tissue and of talc migrating through the human female reproductive tract, the literature reviewed does not provide any convincing evidence that pure cosmetic talc, when used as intended, presents a health risk to women.
Wong (1999)	Case Control Study. Hospital based. Evaluated 499 patients with ovarian cancer and 755 patients with non-gynecological malignancies in Buffalo, NY. Exposure to talc was determined using a self-administered questionnaire. Women were queried on site of talc use (sanitary napkin vs. genital/thigh area) and duration of use.	Women with ever use of talc in genital or thigh region had an odds ratio of **1.0 (0.8-1.3)** and both talc applied to those region and sanitary napkin has an odds ratio of **1.1 (0.7-1.7).** For duration of use of talc, a use of 1-9 years reported an odds ratio of **0.9 (0.6-1.5**); 10-19 years at **1.4 (0.9-2.2)** and greater than or equal to 20 years of **0.9 (0.6-1.2).**	The study has two potential weaknesses. First, as with any retrospective study using data collected from the patients' recall of evens, potential ascertainment and recall bias may exist. Second, condoms and diaphragms are potential sources of talc exposure. The questionnaire asked about these forms of contraception but does not ask about the frequency or duration of usage.	A significant association between the use of talcum powder and the risk of developing epithelial ovarian cancer is not demonstrable, even with prolonged exposure.

	But, the study did not report the questions asked.		Consequently, the study is limited to the use of talc on the perineum or sanitary napkins and does not address potential talc exposure from condom or diaphragm use.	
Cramer (1999)	Case Control Study. Population based. Evaluated 563 women with ovarian cancer and 523 controls in eastern MA and NH areas. Exposure to body powders was ascertained through personal interview. Women were asked if they had "regularly used talc, baby or deodorizing powders dusted or sprayed" to feet, arms, or other non-genital areas, to the genital or rectal area, on sanitary napkins or on underwear. A husband's use of powder in his genital area was also assessed. Age at first use, types of powders, applications per month and total years of use were assessed. Potential exposure from condoms or diaphragms was not assessed.	Women with any genital exposure had an adjusted odds ratio of **1.60 (1.18-2.15).** For frequency per month, women with less use less than 30 had an odds ratio of **2.21 (1.37-3.56)** whereas with 40+ use had an odds ratio of **1.57 (0.8-3.10).** Women with serous invasive ovarian cancer had an adjusted odds ratio of **1.7 (1.22-2.39)**	The relatively weak odds ratios observed could reflect potential biases, especially recall and confounding. Recall bias is possible because talc exposure in these studies is based on person recollection. However, recall bias seems more likely to affect exposures that have occurred over a short term than those that have occurred over long term. If publicity regarding the association correlated with selective recall, one might expect a trend for cases from more recent studies to report higher exposure rate. As to confounding, the authors found no evidence that genital talc exposure varied by key risk factors for ovarian cancer such as age, parity, OC use. The demonstrated consistent association between talc and ovarian cancer appears to be unlikely to be explained by recall or confounding. In attempting to address the lack of a clear dose response, the authors point out that it is difficult to quantify the	In summary, we have demonstrated a consistent association between talc and ovarian cancer that appears unlikely to be explained by recall or confounding. The dose-response relationship is weak but improved by considering factors such as closure of the female tract, ovulation and exposure prior to pregnancy, and we have outlined a plausible biologic rationale for this association. We estimate that avoidance of talc in genital hygiene might reduce the occurrence of a highly lethal form of cancer by at least 10%. Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex. Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.

			amount of powder actually used and degree of perineal dusting that might constitute an "application of talc," Other considerations include the use during ovulation and closure of tract as a result of tubal ligation or hysterectomy.	
Ness (2000)	Case Control Study. Hospital based. Evaluated women with ovarian cancer ascertained from 39 hospitals in Eastern Pennsylvania, Southern New Jersey, and Delaware. 767 cases of ovarian cancer were interviewed, with 1,367 population-based controls. Talc exposure was determined by asking women if they ever used talc, baby, or deodorizing powder at least once per month for 6 or more months in their genital or rectal area, on sanitary napkins, on underwear, on a diaphragm or cervical cap, or on non-genital areas. They also were asked about male partner use of talc to the genital area or underwear.	Compared with never-users, women who used talc in genital/rectal areas had an elevated odds ratio for ovarian cancer of **1.5 (1.1-2.0).** Users on sanitary napkins had an increased risk for ovarian cancer with an odds ratio **1.6 (1.1-2.3).** Use on underwear increased risk to an odds ratio of **1.7 (1.2-2.4).** Use on a diaphragm/cervical cap or by a male partner did not increase risk. Among those who used in the genital/rectal or other body areas did not show increasing risk with increasing numbers of years of use.	A limitation of the study was the somewhat low participation rate among cases and controls. Another limitation is the potential for recall bias, which is a concern with any case-control study. However, in this study recall bias is unlikely to explain factors that appear to be protective, which was the case for many of the associations found. A final limitation is that many of the effect sizes were modest.	Talc use on all areas of the body elevated ovarian cancer risk, even after adjustment for potentially important confounding factors. Environmental factors and medical conditions that increased the risk included talc use…. The spectrum of associations provides support for the hypothesis that inflammation may mediate ovarian cancer risk.
Mills (2004)	Case Control Study. Population based. Evaluated 256 cases from cancer registries and 1,122	Ever use of perineal talc had an increased risk for ovarian cancer with an odds ratio **1.37 (1.02-1.85).** Increasing frequency of use was	The sample size was relatively small and the response fraction lower than ideal. Recall bias has been	This study provides some support for the hypothesis that perineal talc use is associated with an increased risk for epithelial ovarian cancer.

	population-based controls from in 22 counties of Central California. Women were queried about their talcum powder use in the genital area, years of use, frequency of use, and total duration of use. Invasive and borderline tumors were studied.	associated with increasing risk-women using talc 4-7 times per week had an odds ratio of **1.74 (1.14-2.64)** for ovarian cancer (p=0.015). There was an indication of trend with duration of use up to 4-12 years OR **1.86 (1.16-2.98),** but the number of years beyond that did not increase risk further. A similar relationship was found for cumulative dose (frequency x duration) and risk peaked in second and third quartiles (p=0.051). Risk for women with serous invasive tumors had an odds ratio of **1.77 (1.12-2.81).**	implicated…. It has also been suggested that use of talc is habitual versus memorable and not likely to be subject to recall bias. Treatment effect is also a limitation.	The precautionary principal should be invoked, especially given that this is serous form of cancer, usually associated with a poor prognosis, with no current effective screening tool…. Unlike other forma of environmental exposures, talcum powder use is easily avoidable.
Merritt (2008)	Case Control Study. Population based. Evaluated 1,576 women with ovarian cancer and 1,509 population-based controls from Australia. Women provided information on self-administered questionnaires. To determine use of talcum powder in the perineal region, participants were asked if they had ever used powder or talc in the genital area, on underwear, or on sanitary pads/diaphragms. They were also asked about age at first use and years of talc use in these areas. Duration of talcum powder use prior to and after surgical	Ever use of talc in the perineal region was associated with an odds ratio of **1.17 (1.01-1.36).** The increase was strongest for serous with an odds ratio **1.21 (1.03-1.44)** and was also seen for endometrioid with an odds ratio **1.18 (0.81-1.70).** A trend for duration of use greater than 25 years was seen for all cases with an odds ratio of **1.29 (1.04-1.58) p=0.021).**	Low response rate for controls (47%), which could have resulted in selection bias and possibly lead to an over-representation of health subjects among the controls. Additionally, the analysis of the medical conditions was based entirely on self-reported medical history and as a result the accuracy of these reports could not be confirmed, although self-reports of these miscellaneous conditions are unlikely to be influenced greatly by case/control status.	Former studies together with the current findings support the hypothesis that talc particles are transported to the ovaries via unobstructed fallopian tubes. Focusing on talc use, we found that any use of perineal talc was associated with a small but significantly increased risk of ovarian cancer overall and specifically amongst the invasive and LMP serous tumours although no clear dose-response with increasing duration of use was identified. This finding is consistent with results of previous studies. We conclude that on balance chronic inflammation does not play a major role in the development of ovarian cancer.

	sterilization was calculated, and all analyses were limited to the time when the fallopian tubes would have been patent. Use of talc on arms, chest or abdomen was also collected.			
Moorman (2009)	*Case control. Population based. Investigated 1,114 cases with histopathologically confirmed tumors as part of the North Carolina Ovarian Cancer Study conducted in a 48-county region of North Carolina. Control women were frequency-matched by age and race/ethnicity. Talc exposure was ascertained through in-person interviews and questionnaire conducted by nurses.*	*After adjusting for age there was an increased risk for ovarian cancer with (ever/never) talc use reported for both whites with an odds ratio of 1.04 (0.82 -1.33) and African American of 1.19 (0.68-2.09).*	The North Carolina Ovarian Cancer Study included more African-American women that any other study of ovarian cancer, but the relatively small sample made it difficult to ascertain which association were true associations and which were due to chance findings. Other limitations included the case-control method. The possibility of bias being introduced due to nonparticipation of ovarian cancer cases and controls should be considered.	The relative importance of ovarian cancer risk factor may differ for African-American women but conclusions were limited by the small sample.
Wu (2009)	*Case control. Population based. Evaluated 609 women with newly diagnosed epithelial ovarian cancer and 688 population-based control women residing in Los Angeles county, CA. Talc exposure was determined through a comprehensive questionnaire that used a reference date of 2 years before the date of diagnosis (or date of interview for controls).*	*After adjusting for race, age, education, tubal ligation, family history, menopausal status, use of oral contraceptives, and parity ever perineal use of talc was associated with an increased relative risk of ovarian cancer 1.53 (1.13-2.09). The risk of ovarian cancer increased significantly with increasing frequency and duration of talc use; compared to never users risk and was highest among long duration (20 years), frequent (at least daily) talc users with an adjusted relative risk of 2.08 (1.34-*	Confounding, bias.	The role of talc in the development of ovarian cancer has been studied extensively. In a 2006 review by the International Agency for Research on Cancer (IARC), talc was classified as possibly carcinogenic to humans *(i.e.,* Group 2B) on the basis that most of the 20 epidemiological studies on talc and ovarian cancer show consistently a 30--60% increased risk associated with talc use. However, only about half of the studies examined exposure response relationships and the evidence for this is less consistent. This study adds to

	Subjects were asked if they ever used talc at least once per month for 6 months or more. If the response was positive, they were asked if they had ever used talc in non-perineal areas, perineal areas or on underwear or sanitary pad/diaphragm. Questions on talc use included age at first use, frequency of use (times per month) and years of talc use.	*3.23). The association between talc use and risk of ovarian cancer was strongest for serous ovarian cancer with a relative risk for any use of 1.70 (1.27-2.28).*		small group of studies that have investigated the combination of frequency and duration of talc use and ovarian cancer. Results show a significant trend with increasing number of total applications. The results also suggest that talc use prior to 1976 may be more important. The lack of sufficient information on frequency, duration and calendar period of talc use may have contributed to misclassification of this exposure variable in some previous studies. OK
Rosenblatt (2011)	Case control. Population based. Evaluated a total of 812 women with ovarian cancer identified through a cancer registry and 1,313 controls from the western Washington population. Sources of genital powder were ascertained, including direct perineal application, use on sanitary napkins and diaphragms, and use of deodorant vaginal spray. For powder use on sanitary napkins and use of vaginal deodorant sprays, the authors recorded the total number of months or years in which these products were used. For use of perineal powder, the investigators recorded the age began and ended,	Risk of ovarian cancer with genital powder was associated with an odds ratio **1.27 (0.97-1.66).** The risk for borderline ovarian tumors showed an odds ratio of **1.55 (1.02-2.37)** and for invasive ovarian cancers the odds ratio was **1.27(0.87-1.58).** Use of powder on either sanitary napkins or diaphragms did not increase risk. Use of vaginal deodorant spray showed an odds ratio **1.15 (0.85-1.56).** None of the dose-response or time variables (years of use, lifetime number of applications, age at first use, age at last use, calendar year of first use, time since first year, time since last use) showed evidence of increasing relative risk of ovarian cancer with increasing level of exposure to talcum powder products. Similarly, there was no evidence of increased risk for ovarian cancer with increasing dose	The validity of all of these studies, including this may be influenced by the level of non-response among cases and controls and by the potential for misclassification (differentials and non-differential) of exposure status.	IARC has designated perineal exposure to talc as a possible carcinogen in women. A modest association of ovarian cancer with this exposure was seen in the study and in some previous ones, bur the association generally has not been consistent with or among studies. Therefore, no stronger adjective than "possible" appears warranted at this time. It is not evident how (or if) additional investigation will be able to resolve the issue of whether perineal exposure to talc predisposes to ovarian malignancy. Further case-control studies will continue to be hindered by the limitations mentioned above. Data from additional cohort studies would be welcome, but without details concerning the composition of the powders used by cohort members – details that many participants may not be able to provide – the results of such

	number of weeks or months of use per year, and average days per week used. Study participants were also asked about the types of powder used, including talcum, baby, cornstarch, deodorant, body/bath, and other or unknown. The authors then calculated the lifetime duration of use, and estimated lifetime number of applications.	of powder use on sanitary napkins, or of vaginal deodorant sprays.		studies may similarly be ambiguous in their interpretation. OK
Kurta (2012)	Case Control. Population based. Evaluated 902 cases of women with ovarian cancer and 1,802 controls from resident of Western Pennsylvania, Eastern Ohio, and Western New York State. Perineal talc use was defined as ever using dusting powder or deodorizing spray on the genital or rectal areas, on sanitary napkins, on underwear, or on diaphragms or cervical caps.	Use of perineal talc showed an increased risk for ovarian cancer with an odds ratio **1.40 (1.16–1.69).**	Reliance on self-reported use of study drugs and talc- recall bias.	Concludes that risk of ovarian cancer is significantly associated with talc use. Compared to Caucasians, African Americans had a significantly increased risk of ovarian cancer. The following variables were also significantly associated with ovarian cancer risk: age at menarche, OC use, parity, gravidity, duration of breastfeeding, perineal talc use, and tubal ligation. OK
Wu (2015)	Case Control. Population based. Investigated the associations of risk of ovarian cancer and talcum powder products use and other risk factors. 1,701 cases were identified	Use of genital talc for one year or more in combined ethnicities was associated with an increased risk for ovarian cancer with an odds ratio **1.46 (1.27-1.69).** Similar relative risks were seen in non-Hispanic white, Hispanic, and African-American women. For 5 years	Small sample sizes for Hispanics and African Americans	Population attributable risk percentages (PAR%s), defined as the percentages of disease in the population that are attributable to a given risk factor (or set of risk factors), were calculated. The risk associations with six well-accepted factors (parity, oral contraceptive use,

	through the SEER population-based University of Southern California cancer registry. and 2,319 controls were recruited from the cases' neighborhoods using random selection from population lists. In-person interviews were conducted. To determine use of talcum powder, women were asked if they ever used talc at least once per month for 6 months or more. If the response was positive, they were asked whether they had ever used talc in non-perineal areas (feet, arms, chest or back), perineal areas, or on underwear or sanitary pads/diaphragm. Questions on talc use included age at first use, frequency of use (times per month) and years of talc use.	increments of genital talc use, the risk for ovarian cancer increased with an odds ratio of **1.14 (1.09-1.20).**		tubal ligation, endometriosis, family history of ovarian cancer, and talc use) were comparable and significant in Hispanics, AA, and non-Hispanic whites. As expected, each of these six risk factors had statistically significant effects on risk in all three groups.
Cramer (2016)	Case control. Population based. Reported on association between genital talc use and risk of ovarian cancer. Evaluated 2,041 cases of ovarian cancer from tumor boards and registries in Eastern Massachusetts and Massachusetts and 2100 controls identified from the sample population as controls. Participants were	Genital talc use was associated with an increased risk of ovarian cancer with an odds ratio of **1.33 (1.16-1.52).** Reported a significant trend for greater ovarian cancer risk with increasing talc-years of use. > 7,200 apps (equivalent to >20 years of daily use showed an odds ratio **1.49 (1.06-2.10).**	Recall bias. There are no external records to validate talc use reported by study participants to assess whether our degree of misclassification is reasonable. Whether the association is a result of confounding must be addressed. No evidence of confounding was identified but authors did find several examples of effect	Overall, there is an association between genital talc use and EOC and a significant trend with increasing "talc years" of use. Among many epidemiologic variables, no confounders for the association were identified. The association may be stronger in AA women. OK

	asked if they "regularly" or "at least monthly" applied powder to the genital or rectal area, sanitary napkins or tampons, underwear, or non-genital areas. Type of powder, age begun, years used, and applications per month were ascertained. Lifetime exposure was estimated by multiplying frequency of applications per month by months used, and talc-years was calculated. Participants were then divided into quartiles according to these variables. Participants were also asked if their partners dusted or sprayed powder to their genital or rectal areas. Condom and diaphragm use were ascertained as potential sources of genital talc exposure.		modification that have biological relevance: prolactin may be mediator. There are inherent limitations quantifying a dose–response due to a lack of metrics for how much talc is in an "application," how much enters the vagina, and how much reaches the upper genital tract where, presumably, any deleterious effect is mediated. This may account for the failure to identify a dose–response in many papers on talc and ovarian cancer.	
Schildkraut (2016)	Case control. Population based. Investigated the association between body powder use and ovarian cancer in African American women in 11 geographic areas of the U.S. Evaluated 584 case identified through SEER cancer registries or through hospital departments and 745	Use of genital powder was associated with an odds ratio **1.44 (1.11-1.86).** A dose response was found for duration of use (> 20 years was associated with an odds ratio of **1.52 (1.11-2.07)** and number of lifetime applications **(P trend 1.14)** and daily use of genital powder showed an odds ratio of **1.71 (1.26-2.33.)** Histological analysis revealed an odds ratio of **1.38 (1.03-1.85**) for serous and	Result could have been spurious do to underreporting of genital talc and sample size may have been too small.	Study showed that genital powder use was associated with ovarian cancer risk in AA women and are consistent with localized chronic inflammation in the ovary due to particulates that travel through a direct transvaginal route. The dose response observed for duration of genital powder use provides further evidence for the relationship between genital powder and overall EOC risk. Data suggest an increased risk for serous and non-

	controls. Controls were randomly selected from the same populations as the cases. Participants were questioned via phone interview whether they had ever regularly used talc, cornstarch, baby, or deodorizing powders. Women were classified as "regular users" if they reported using any of these powders at least monthly for at least 6 months, and "never users" otherwise. Regular users were asked about frequency and duration of use; use on genital areas, underwear, sanitary napkins, or diaphragms; and use on non-genital areas. Lifetime number of applications was estimated as number of applications per month times number of months used. Occupational exposure (yes/no) was ascertained for a subset of participants.	genital use of powder and **1.63 (1.04-2.55**) for non-serous.		serous subtypes with use of genital powder. The results of the current study suggest that the use of body powder is an especially important modifiable risk factor for EOC in AA women.

III. META-ANALYSES

AUTHOR	STUDY DESCRIPTION	FINDINGS	REPORTED LIMITATIONS	AUTHORS' DISCUSSION AND CONCLUSIONS
Harlow (1992)	Meta-Analysis of 6 studies with 1106 cases	Statistically significant OR of 1.3 for any perineal talc exposure Daily vs. <daily talc use and talc use >10 years vs. <10 years were associated with greater risk for ovarian cancer.	Cannot rule out the possibility in differential over- or under-reporting of talc exposure in cases and controls	Because the overall association between genital use of talc and ovarian cancer remains weak, it is unlikely that this exposure-disease pathway is the principal one involved in ovarian cancer etiology. The authors concluded that they calculate that by applying these odds ratios to the exposure rate among cases, the proportion of ovarian cancer incidence attributable to this level of talc exposure is about 10%. They further state that given the poor prognosis for ovarian cancer, any potentially harmful exposures should be avoided, particularly those with limited benefits. For that reason, they discouraged the use of talc in genital hygiene, particularly as a daily habit.
Gross & Berg, 1995	OR = 1.27 Pooled 10 studies – 614 cases Supported by J&J	1.27 (95%CI, 1.09-1.48)	Other risk factors were not adjusted for in a consistent manner across studies. Selection bias and differential bias were not addressed specifically in the studies.	The body of knowledge found in the medical literature does not unequivocally support the hypothesis that talc use by women puts them at an increased risk of ovarian cancer. However, the results of the meta-analyses do suggest the possibility of an increased risk of ovarian cancer due to perineal talc use. Further research in this area *is* warranted by these results.
Cramer, 1999	Meta-analysis Pooled 14 studies plus Cramer 1999 Attributable Risk of 10-11% Ruled out recall bias Grant by NCI	1.36 (95%CI, 1.24-1.49)	Recall: Recall bias seems more likely to affect exposures that have occurred over a short term than those that have occurred over a long term. Since average duration of talc use exceeded 20 years in both	There is a consistent association between talc and ovarian cancer that appears unlikely to be explained by recall or confounding. The dose-response relationship is weak but improved by considering factors such as closure of the female tract, ovulation and exposure prior

			cases and controls in our current study, genital talc exposure may be less likely to be subject to recall bias. Furthermore, if publicity regarding the association correlated with selective recall, one might expect a trend for cases from more recent studies to report higher exposure rates, but the exposure rates reported do not suggest this is the case. It also seems reasonable that selective recall would lead to cases reporting all types of talc exposure more frequently than controls, but our study found that cases did not report a significant excess of talc use in non-genital areas compared to controls. Confounding: Authors found no evidence that genital talc exposure varied by key risk factors for ovarian cancer such as age, parity or OC use and little variability of the association by these and other variables.	to pregnancy, and we have outlined a plausible biologic rationale for this association. Authors estimated that avoidance of talc in genital hygiene might reduce the occurrence of a highly lethal form of cancer by at least 10%. Balanced against what are primarily aesthetic reasons for using talc in genital hygiene, the risk benefit decision is not complex. Appropriate warnings should be provided to women about the potential risks of regular use of talc in the genital area.
Huncharek, 2003[54]	Meta-analysis RR = 1.33 16 studies No disclosure regarding industry relationship.	1.33 (95%CI, 1.16-1.45)	The meta-analysis presented shows inconsistencies in the available data. The summary relative risk may be spurious due to bias or uncontrolled confounding.	Despite the finding of a positive association, demonstration of a dose-response relationship is an important criterion for making causal inferences from epidemiological data. If no relationship exists, a causal link

[54] Dr. Muscat and Huncharek were consulting with Johnson & Johnson at the time of this publication. In October 2000, Dr. Huncharek solicited finding for an Ovarian Cancer Meta-Analysis from J&J to be performed by he and Dr. Muscat and he provided J&J with "preliminary results" of his analysis in November 2000. Deposition of Susan Nicholson, dated July 26, 2018; Deposition of Linda Loretz, Ph.D., dated October 1, 2018. In November 2000, J&J, through its senior scientist, John Hopkins provided editorial comments to Dr. Huncharek' s preliminary results that would more strongly refute the relationship between asbestos and talc and causation. JNJ 000377405. These 2000 J&J comments were ultimately incorporated into the final Huncharek Meta-Analysis which was submitted in 2002 and published in 2003.This relationship was not disclosed.

				between exposure and disease is questionable. Asbestos contamination of talc has been identified in the past but current production methods limit or completely eliminate contamination. In summary, pooling data from the sixteen available observational studies examining the relationship between perineal use of cosmetic talc and the development of invasive epithelial ovarian cane.er failed to show evidence of a causal relationship.
Langseth, 2008	Meta-analysis 20 case-control studies; one cohort (Gertig) No studies below 1.0 RR IARC review Financed by the Cancer Registry of Norway	1.35 (95%CI, 1.26-1.46) Pooled OR = 1.35 (1.26-1.46)	Methodological factors such as recall bias should always be considered in case-control studies. It could have been a problem had there been widespread publicity about the possible association between use of body powder and cancer. The International Agency for Research on Cancer (IARC) working group considers that there has not been widespread public concern about this issue and therefore considers it unlikely that such a bias could explain the consistent findings. Another source of recall bias could result from the fact that women with the cancer tend to remember or overreport	The evidence in favor of an association, a very large number of studies have found that women who used talc experienced excess risks of ovarian cancer; some results were statistically significant and some were not. There was some indication in the cohort study of an increase in serous tumours. The evidence of talc migrating to the ovaries lends credibility to such a possible association. The main epidemiological evidence against the association is the absence of clear exposure-response associations in most studies, as well as the absence of an overall excess risk in the cohort study. On balance, the epidemiological evidence suggests that use of cosmetic talc in the perineal area may be associated with ovarian cancer risk. The mechanism of carcinogenicity may be related to inflammation. High degree of consistency among studies.

			their use of body powder. The influence of this type of recall bias cannot be ruled out.	The carcinogenicity of non-asbestiform talc was assessed by a monograph working group at IARC in 2006. After considering biases and possible confounding factors, the IARC working group concluded that the epidemiological studies provided limited evidence for the carcinogenicity of perineal use of talc-based body powder, and classified this use as possibly carcinogenic to human beings (that is, group 2B). The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk.
Berge, 2017	Meta-analysis 24 case-control studies and three cohort studies 302,705 women	Summary RR =1.22 (95%CI, 1.13-1.30) Case-control studies = RR 1.26; cohort studies = 1.02 Serous carcinoma RR = 1.24 There was no trend in RR with either duration or frequency of genital talc use.	The heterogeneity of results by study design and the lack of a trend for duration and frequency of use, however, detract from a causal interpretation of this association.	This meta-analysis resulted in a weak but statistically significant association between genital use of talc and ovarian cancer, which appears to be limited to serous carcinoma.
Penninkilampi, 2018	Meta-analysis 24 case-control (13, 421 cases) and three cohort studies (890 cases, 181,860 person-years)	Any perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50).	A limitation of this study is that it pools nonrandomized studies, primarily case–control studies. The retrospective nature of case–control studies introduces the potential for recall bias. In this case, it is entirely possible that patients with ovarian cancer may be	Hence while case–control studies are low-level evidence, they have been preferred in the investigation of the association between talc use and ovarian cancer. They also have the important advantage of not requiring 15 or more years of follow-up, as is necessary for a cohort study to sufficient detect cases of ovarian cancer relative to certain exposures. One potential way to overcome this

		An association with ever use of talc was found in case–control studies (OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55).	more aware of their previous talc use and hence be more likely to report higher past use. It is possible to attempt to overcome this by blinding the participants to the nature of the study, usually by asking spurious questions; however, the effectiveness of this approach may be limited. Many of the studies in this review recorded data about talc use as part of a more extensive questionnaire focused on other associations, which may reduce the potential for recall bias. However, since the initiation of lawsuits in 2014, there has been extensive media coverage regarding this association, and the potential for recall bias in case–control studies conducted since then may be exacerbated.	limitation in future studies is to ensure that talc use is always included in questionnaires of any cohort studies investigating ovarian cancer. It is important not only that talc use be investigated but also the precise location, duration, and frequency of use. As it stands, a meta-analysis of observational studies such as the present study provides the highest level of evidence practically feasible for this research question. The results of this review indicate that perineal talc use is associated with a 24%–39% increased risk of ovarian cancer. While the results of case–control studies are prone to recall bias, especially with intense media attention following the commencement of litigation in 2014, the confirmation of an association in cohort studies between perineal talc use and serous invasive ovarian cancer is suggestive of a causal association.
Terry, 2013	Pooled analysis RR = 1.24 (1.15-1.33) 8 population based studies; 8,525 cases and 9,859 controls (2600 exposed cases) Pooled study; authored by OCAC	Any perineal talc use was associated with increased risk of ovarian cancer (OR = 1.31; 95% CI = 1.24, 1.39). More than 3600 lifetime applications (OR = 1.42; 95% CI = 1.25, 1.61) were slightly more associated with ovarian cancer than <3600 (OR = 1.32; 95% CI = 1.15, 1.50). An association with ever use of talc was found in case–control studies	Differences in the wording of questions about genital powder use and retrospective nature of the exposure ascertainment. This results in varying levels of misclassification of true exposure. There was missing data, but was not likely to bias results, according to authors	In conclusion, our large pooled analysis of case-control studies shows a small-to-moderate (20–30%) increased risk of ovarian cancer with genital-powder use, most clearly pertaining to non-mucinous epithelial ovarian tumors. More work is needed to understand how genital powders may exert a carcinogenic effect, and which constituents (e.g. talc) may be involved. Since there are few modifiable risk factors for ovarian cancer, avoidance of genital powders

		(OR = 1.35; 95% CI = 1.27, 1.43), but not cohort studies (OR = 1.06; 95% CI = 0.90, 1.25). However, cohort studies found an association between talc use and invasive serous type ovarian cancer (OR = 1.25; 95% CI = 1.01, 1.55).		may be a possible strategy to reduce ovarian cancer incidence. The biologic plausibility for the observed association between genital-powder use and ovarian cancer risk has been challenged because evidence for dose-response has been inconsistent. The lack of significant dose-response may reflect the difficulty inherent in accurate recollection of specific details of frequency and duration of genital-powder use. Alternatively, the association between genital-powder exposure and ovarian cancer risk may not be linear and a modest exposure may be sufficient to increase cancer risk. When unexposed group was included in the analysis there was a clear dose response w/ increased number of applications

APPENDIX A: RESUME

DAVID A. KESSLER

1969-1973	AMHERST COLLEGE, Amherst, Massachusetts Bachelor of Arts, *magna cum laude* (B.A. Independent Scholar, 1973)
1973-1979	HARVARD MEDICAL SCHOOL, Boston, Massachusetts Doctor of Medicine (M.D. 1979)
1975-1977	UNIVERSITY OF CHICAGO LAW SCHOOL, Chicago, Illinois Doctor of Law (J.D., 1978), Harvard Law School, 1977-1978
1984-1986	NEW YORK UNIVERSITY GRADUATE SCHOOL OF BUSINESS ADMINISTRATION (Manhattanville), Purchase, New York Advanced Professional Certificate in Management

EMPLOYMENT

2003-present	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO Professor of Pediatrics, Epidemiology and Biostatistics
2003-2007	Dean, School of Medicine Vice Chancellor of Medical Affairs
1997-2003	YALE UNIVERSITY SCHOOL OF MEDICINE Dean Professor of Pediatrics, Internal Medicine, and Public Health
1990-1997	UNITED STATES FOOD AND DRUG ADMINISTRATION Commissioner (Appointed by President George H. W. Bush, Reappointed by President William J. Clinton)
1984-1990	THE HOSPITAL OF THE ALBERT EINSTEIN COLLEGEOF MEDICINE Medical Director
1986-1990	COLUMBIA UNIVERSITY Julius Silver Program in Law, Science and Technology Lecturer on Law
1982-1984	MONTEFIORE MEDICAL CENTER Special Assistant to the President
1981-1984	UNITED STATES SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES, Consultant to the Chairman

HONORARY DEGREES

1992	AMHERST COLLEGE, Amherst, Massachusetts Doctor of Science *honoris causa*
1992	GEORGE WASHINGTON UNIVERSITY, Washington, D.C. Doctor of Science *honoris causa*
1993	PHILADELPHIA COLLEGE OF PHARMACY AND SCIENCE, Philadelphia, Pennsylvania, Doctor of Science *honoris causa*
1993	DICKINSON COLLEGE OF LAW, Carlisle, Pennsylvania Doctor of Laws *honoris causa*
1995	ALBANY MEDICAL COLLEGE, Albany, New York Doctor of Science *honoris causa*
1997	NORTHEASTERN UNIVERSITY, Boston, Massachusetts Doctor of Science *honoris causa*
1998	MOUNT SINAI SCHOOL OF MEDICINE, New York, New York Doctor of Humane Letters *honoris causa*
1998	COLGATE UNIVERSITY, Hamilton, New York Doctor of Science *honoris causa*
1998	YALE UNIVERSITY, New Haven, Connecticut Master of Arts *privation*
1999	CONNECTICUT COLLEGE, New London, Connecticut Doctor of Humane Letters *honoris causa*
2001	DICKINSON COLLEGE, Carlisle, Pennsylvania Doctor of Science, *honoris causa*
2001	UNION COLLEGE, Schenectady, New York Doctor of Laws, *honoris causa*
2002	UNIVERSITY OF LOUISVILLE, Louisville, Kentucky Doctor of Public Service, *honoris causa*
2005	STATE UNIVERSITY OF NEW YORK, Syracuse, NY Doctor of Science, *honoris causa*

2012 DREXEL UNIVERSITY, Philadelphia, PA
Doctor of Science, *honoris causa*

2013 CLAREMONT GRADUATE UNIVERSITY, Claremont, CA
Doctor of Science, *honoris causa*

HONORS

NATIONAL ACADEMY OF SCIENCES, Public Welfare Medal,
Honorary Member

INSTITUTE OF MEDICINE, Member

AMERICAN SOCIETY OF CLINICAL ONCOLOGY
Distinguished Service Award for Scientific Achievement

AMERICAN ACADEMY OF ARTS AND SCIENCES, Fellow

PHI BETA KAPPA, Amherst College

UNIVERSITY OF CHICAGO LAW REVIEW, Associate Editor

2008 PUBLIC HEALTH HERO AWARD, UC Berkeley

SIGMA XI, The Scientific Research Society of North America

BARNARD COLLEGE Barnard
Medal of Distinction

CASPAR PLATT AWARD, The University of Chicago Law School

HARVARD BLODGETT AWARD IN BIOLOGY, Amherst College

WHITING FOUNDATION GRANT-IN-AID for research at
Sloan-Kettering Institute

NATIONAL SCIENCE FOUNDATION FELLOWSHIP (declined)

JOHN WOODRUFF SIMPSON FELLOWSHIP, awarded by Amherst
College for the study of medicine

ALVAN T.--VIOLA D. FULLER AMERICAN CANCER SOCIETY
JUNIOR RESEARCH FELLOW (declined)

NATIONAL INSTITUTES OF HEALTH TRAINING FELLOWSHIP
RECIPIENT for physiology research at the Marine Biological Laboratory,

Woods Hole, Massachusetts

PHI DELTA THETA SCHOLARSHIP
DISTINGUISHED PUBLIC SERVICE AWARD
The George Washington University School of Medicine and Health Sciences

UNITED STATES DEPARTMENT OF JUSTICE, CIVIL DIVISION
Special Citation

AMERICAN SOCIETY OF PUBLIC ADMINISTRATION
National Capitol Area Chapter
President's Award for Outstanding Achievement

AMERICAN FEDERATION FOR AIDS RESEARCH (AmFAR)
Sheldon W. Andelson Public Policy Achievement Award

THE WOODROW WILSON AWARD FOR DISTINGUISHED GOVERNMENT SERVICE Johns Hopkins University

HAL OGDEN AWARD
Association of State and Territorial Directors of Health Promotion and Public Health Education and the U. S. Centers for Disease Control

NATIONAL ORGANIZATION FOR RARE DISEASES (NORD)
Outstanding Service to the Public Health Award

MARCH OF DIMES
Franklin Delano Roosevelt Leadership Award

CHILDREN'S HOSPITAL NATIONAL MEDICAL CENTER
Children's Research Institute Award of Academic Excellence

AMERICAN HEART ASSOCIATION
National Public Affairs Special Recognition Award for Food Labeling

ISRAEL CANCER RESEARCH FOUNDATION
President's Award

INSTITUTE FOR ADVANCED STUDIES IN IMMUNOLOGY AND AGING
Lifetime Public Service Award

AMERICAN LUNG ASSOCIATION
Special Recognition Award

UNIVERSITY OF CHICAGO ALUMNI ASSOCIATION
Professional Achievement Award (Washington, D.C. Chapter)

U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Secretary's Award for Excellence in Public Service

NATIONAL KIDNEY CANCER ASSOCIATION
Progressive Leadership Award

JOHNS HOPKINS UNIVERSITY SCHOOL OF PUBLIC HEALTH
Dean's Medal

AMERICAN CANCER SOCIETY
Medal of Honor

AMERICAN HEART ASSOCIATION
Meritorious Achievement Award

WORLD HEALTH ORGANIZATION Pan
American World Health Organization World
No Tobacco Day Award

AMERICAN HEART ASSOCIATION
National Public Affairs Special Recognition Award for Tobacco

PROFESSIONAL ACHIEVEMENT CITATION, University of
Chicago Alumni Association

PENNSYLVANIA HOSPITAL Molly
and Sidney N. Zubrow Award

AMERICAN LUNG ASSOCIATION OF CONNECTICUT
Humanitarian Award

AMERICAN COLLEGE OF PREVENTIVE MEDICINE
Special Recognition Award

ASSOCIATION OF AMERICAN MEDICAL COLLEGES AND THE ROBERT WOOD JOHNSON FOUNDATION
David E. Rogers Award for Improving Health and Healthcare of the American People

JACOBS INSTITUTE OF WOMEN'S HEALTH
Excellence in Women's Health Award

NARAL PRO-CHOICE AMERICA
Lifetime Achievement Award

THE ASSOCIATION OF STATE AND TERRITORIAL CHRONIC DISEASE PROGRAM DIRECTORS
Joseph W. Cullen Award for Outstanding Contributions to Chronic Disease Prevention and Control

THE COLLEGE OF WILLIAM & MARY LAW SCHOOL
2005 Benjamin Rush Medal

CALIFORNIA CENTER FOR PUBLIC HEALTH ADVOCACY
David Kessler Award for Extraordinary Contribution to the Public Health

BOOKS FOR A BETTER LIFE AWARD

INTERNSHIP & RESIDENCY

1981-1982	SENIOR ASSISTANT RESIDENT, Department of Pediatrics, The Johns Hopkins Hospital
1980-1981	ASSISTANT RESIDENT, Department of Pediatrics, The Johns Hopkins Hospital
1979-1980	INTERN, Department of Pediatrics, The Johns Hopkins Hospital

ACADEMIC APPOINTMENTS

2003-present	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO Professor of Pediatrics Professor of Epidemiology and Biostatistics
1997-2003	YALE UNIVERSITY Professor of Pediatrics Professor of Internal Medicine Professor of Public Health
1990-1997 (On leave)	ALBERT EINSTEIN COLLEGE OF MEDICINE Department of Pediatrics Department of Epidemiology and Social Medicine Associate Professor of Pediatrics Associate Professor of Epidemiology and Social Medicine
1988-1990	ALBERT EINSTEIN COLLEGE OF MEDICINE Department of Epidemiology and Social Medicine Assistant Professor
1986-1990	COLUMBIA UNIVERSITY SCHOOL OF LAW Julius Silver Program in Law, Science and Technology Lecturer on Law

1982-1990 ALBERT EINSTEIN COLLEGE OF MEDICINE
Department of Pediatrics
Assistant Professor

SPECIAL STUDY

June 1987 JOHNS HOPKINS SCHOOL OF HYGIENE AND PUBLIC HEALTH
Graduate Summer Program in Epidemiology - Pharmacoepidemiology

June 1985 YALE SCHOOL OF ORGANIZATION AND MANAGEMENT
Advanced Management Studies in Health Care Management

1977-1978 HARVARD LAW SCHOOL, Special Student

RESEARCH EXPERIENCE

Summers 1970-1972 SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH
Division of Drug Resistance, New York, New York
Research Asst

Summer 1972 MARINE BIOLOGICAL LABORATORY, Woods Hole, Massachusetts
Physiology course

1974-1975 CHILDREN'S HOSPITAL MEDICAL CENTER
Department of Surgical Research, Boston, Massachusetts
Research Associate

Summer 1976 DEPARTMENT OF HEALTH, EDUCATION and WELFARE
Office of the General Counsel, Chicago, Illinois
Law Clerk

VISITING COMMITTEE

1992-1994 UNIVERSITY OF CHICAGO LAW SCHOOL

UNIVERSITY ACCREDITATION

2008-2012 WESTERN ASSOCIATION OF SCHOOLS AND COLLEGES,
Chair of LLU Accreditation Committee

2013-2015 NORTHWEST COMMISSION ON COLLEGES AND UNIVERSITIES
University of Washington

SPECIAL PROJECTS

1982-1988 THE ROBERT WOOD JOHNSON FOUNDATION
Program for Hospital Initiatives in Long-Term Care,

1989-1990 THE PEW CHARITABLE TRUSTS
THE ROBERT WOOD JOHNSON FOUNDATION
Program to Strengthen Hospital Nursing Co-Director

CORPORATE BOARD AND ADVISORY POSITIONS AND COMMITTEES

2011 - Present IMMUCOR
Member of Board, Chairman of Compliance Committee

2008 - Present TPG
Senior Advisor

2011 - 2014 APTALIS HOLDINGS
Member of Board, Chairman of Compliance Committee

2009 –2017 TOKAI
Member of Board

2007 GOOGLE HEALTH ADVISORY COUNCIL

2007 REVOLUTION HEALTH GROUP
Medical Advisory Board

2007 PERSEUS LLC
Advisory Board

2003 – 2014 FLEISHMAN HILLARD INTERNATIONAL COMMUNICATIONS
International Advisory Board

2000 - 2003 PERSEUS-SOROS BIOTECHNOLOGYFUND Scientific Advisory Board

ADVISORY COMMITTEES

2007 THE RHODES TRUST, THE RHODES SCHOLARSHIPS
Chair, California Selection Committee

2006	CENTER FOR THE ADVANCED STUDIES ON AGING, UNIVERSITY OF MIAMI External Advisory Group
2005 -2015	BROAD MEDICAL RESEARCH PROGRAM Advisory Board
2005	CLINTON SCHOOL OF PUBLIC HEALTH, UNIVERSITY OF ARKANSAS FOR MEDICAL SCIENCES National Advisory Board
2003, 2013	HEINZ AWARDS (HEINZ FAMILY FOUNDATION) Awards Juror
2003	MARCH OF DIMES Chair, Prematurity Campaign in Northern California
2002 - 2004	CENTERONALCOHOLMARKETINGANDYOUTHATGEORGETOWN UNIVERSITY Advisory Board
2001 -	UNIVERSITY OF CHICAGO LAW REVIEW Editorial Advisory Board
2000 - 2005	JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION Oversight Committee
2000	GOVERNOR'S BLUE RIBBON COMMISSION ON MENTAL HEALTH, STATE OF CONNECTICUT Honorary Chair
2000	FILM AID INTERNATIONAL, INTERNATIONAL RESCUE COMMITTEE Advisory Board
1999	WORLD HEALTH ORGANIZATION Expert Panel on Tobacco
1997	ADVISORY COMMITTEE ON TOBACCO AND PUBLIC HEALTH (Co-Chairman with C. Everett Koop)
1993	GOVERNMENT UNIVERSITY INDUSTRY ROUNDTABLE National Academy of Sciences
1990	ADVISORY COMMITTEE ON THE FOOD AND DRUG ADMINISTRATION Chairman, Drugs and Biologics Subcommittee
1988 - 1989	NATIONALADVISORYCOUNCILONHEALTHCARETECHNOLOGY ASSESSMENT, Department of Health and Human Services, Washington, D.C. Chairman, Patient Outcomes Subcommittee

PRIOR FEDERAL COMMITTEE MEMBERSHIPS

WHITE HOUSE COMMISSION ON PRESIDENTIAL SCHOLARS

NATIONAL COUNCIL ON SCIENCE AND TECHNOLOGY
Committee on Health, Safety and Food R&D, Vice Chair

INSTITUTE OF MEDICINE
Forum On Drug Development and Regulation

INSTITUTE OF MEDICINE
AIDS Roundtable

NATIONAL TASK FORCE ON AIDS DRUG DEVELOPMENT

OFFICE OF SCIENCE AND TECHNOLOGY POLICY Federal Coordinating Council for Science, Engineering and Technology Committee on Life Science and Health Biotechnology Research Subcommittee, Member ex officio

BOARDS OF DIRECTORS

Current:

CENTER FOR SCIENCE IN THE PUBLIC INTEREST

DRUG STRATEGIES

Past:

AMHERST COLLEGE BOARD OF TRUSTEES

ELIZABETH GLASER PEDIATRIC AIDS FOUNDATION
Chairman, Board of Directors

NATIONAL CENTER FOR ADDICTION AND SUBSTANCE ABUSE
COLUMBIA UNIVERSITY

INTERNATIONAL PARTNERSHIP FOR MICROBICIDES INDEPENDENT CITIZENS OVERSIGHT COMMITTEE OF THE CALIFORNIA INSTITUTE FOR REGENERATIVE MEDICINE

HENRY J. KAISER FAMILY FOUNDATION

DOCTORS OF THE WORLD

YALE-NEW HAVEN HOSPITAL

CONSUMERS UNION

NATIONAL COMMITTEE FOR QUALITY ASSURANCE

NEW YORK COUNTY HEALTH SERVICE REVIEW ORGANIZATION

COMPREHENSIVE MEDICAL REVIEW ORGANIZATION

FELLOWSHIP

YALE COLLEGE Fellow,
Calhoun College

LECTURESHIPS

THE REGIS J. FALLON LECTURE SERIES ON HEALTH AND LAW
University of Chicago

GRAYSON DISTINGUISHED LECTURE
Southern Illinois University School of Law

WEINBERG SYMPOSIUM LECTURE
Harvard Medical School

THE THOMAS B. FERGUSON LECTURE
Society of Thoracic Surgeons

GEORGE E. ALTMAN, M.D. LECTURE
Beth Israel Hospital

BETH AND RICHARD SACKLER LECTURE
University of Pennsylvania

MARTIN W. WITTE LECTURE
Newport Beach Public Library and Newport Beach Public Library Foundation

HERBERT L. ABRAMS LECTURE
Harvard Medical School

GEORGE GOODMAN LECTURE
State University of New York at Stony Brook

EVNIN LECTURE
Princeton University, Woodrow Wilson School

BOYARSKY LECTURE
Law, Medicine, and Ethics, Kenan Ethics Program, Duke University

CHARTER LECTURE
The University of Georgia

GARDERE & WYNNE LECTURE
Health Law and Policy Institute, University of Houston

DISTINGUISHED LECTURE IN NATIONAL SERVICE
University of Miami

TENTH ANNUAL JOHN O. VIETA, MD LECTURE
Lenox Hill Hospital

HARPER FELLOWSHIP LECTURE
Yale Law School

DR. JAMES STEWART KAUFMAN MEMORIAL LECTURE
The Mt. Sinai Health Care Foundation

DULCY B. MILLER MEMORIAL LECTURE
Smith College

JEAN MAYER LECTURE IN NUTRITION AND FOOD POLICY
Tufts University

HENRY BARNETT DISTINGUISHED LECTURESHIP
Albert Einstein College of Medicine

MARTIN A. CHERKASKY DISTINGUISHED LECTURESHIP
Robert Wagner Graduate School of Public Service New York University

ALPHA OMEGA ALPHA DISTINGUISHED LECTURESHIP
Cornell Medical School--New York Hospital

ST. GEORGE SOCIETY LECTURESHIP
Johns Hopkins Medical School

GOVERNOR WINTHROP ROCKEFELLER DISTINGUISHED LECTURESHIP University of Arkansas Medical School

MOLLY AND SIDNEY N. ZUBROW LECTURE
Pennsylvania Hospital

LEROY HOECK M.D. DISTINGUISHED LECTURESHIP
Children's Hospital National Medical Center

JULES AND JANE HIRSH HEALTH POLICY ADDRESS
George Washington University

JOHN S. LATTA LECTURESHIP
University of Nebraska Medical
School

PAUL K. SMITH MEMORIAL LECTURE
George Washington University

WOLK HEART FOUNDATION LECTURE
Colgate University

HASTINGS LECTURE
Association for the Advancement of Medical Instrumentation
National Heart, Lung and Blood Institute

INSTITUTE OF MEDICINE 25TH DISTINGUISHED LECTURESHIP University of Washington

RALPH CAZORT LECTURESHIP
Meharry Medical School

DAVID M. IFSHIN MEMORIAL LECTURE
Potomac, Maryland

CHARLES C. LEIGHTON MEMORIAL LECTURE
Leonard David Institute of Health Economics
University of Pennsylvania

D. W. HARRINGTON LECTURE State
University of New York At Buffalo School of
Medicine and Biomedical Sciences

SAMUEL RUBIN LECTURE FOR THE ADVANCEMENT OF LIBERTY
Columbia University

LEO S. WEIL MEMORIAL LECTURE
Tulane Medical Center, Touro Infirmary,
and Louisiana State University School of Medicine

THOMAS PARRIN LECTURE
University of Pittsburgh School of Public Health

DAVID PACKARD LECTURE
Uniformed Services University of the Health Sciences

NORMAN E. ZINBERG LECTURE
Harvard Medical School

JOHN H. ERSKINE LECTURE
St. Jude's Children's Research Hospital

MARTIN V. BONVENTRE MEMORIAL LECTURE
The Brooklyn Hospital Center

PURVES LECTURE
Woodbridge Library, Woodbridge, Connecticut

VISITING SCHOLAR LECTURE University of Oklahoma - Board of Regents Oklahoma Scholar Leadership Extension Program

J. ROSWELL GALLAGHER LECTURER
Society of Adolescent Medicine

KATHERINE BOUCOT STURGIS LECTURESHIP
American College of Preventive Medicine

HELMUT SCHUMANN LECTURE
Dartmouth-Hitchcock Medical Center

50TH ANNIVERSARY COMMUNICATION LECTURE
Centers for Disease Control and Prevention

5TH JAMES BORDLEY III MEMORIAL LECTURE
Mary Imogene Bassett Hospital

TURNER LECTURE
University of California

MARIE SHULSKY MEMORIAL LECTURE ON HEALTH AND SOCIAL RESPONSIBILITY
Fifth Avenue Synagogue, New York, New York

GERTRUDE AND G.D. CRAIN, JR. LECTURE SERIES
Medill School of Journalism, Northwestern University

GEORGE ARMSTRONG LECTURE
Ambulatory Pediatric Society

ARCO FORUM OF PUBLIC AFFAIRS
Institute of Politics, John F. Kennedy School of Government
Harvard University

PAUL LEVINGER LECTURE AND PROFESSORSHIP PRO TEM IN THE ECONOMICS OF HEALTH CARE Brown University

ARNOLD J. SCHWARTZ MEMORIAL HEALTH LECTURE
Robert F. Wagner Graduate School of Public Service New York University

RONALD ALTMAN MEMORIAL LECTURE
Festival of Arts, Books and Culture, Cherry Hills, New Jersey

SAMUEL MARTIN, M.D. III MEMORIAL LECTURE Division of General Internal Medicine and Leonard Davis Institute University of Pennsylvania

CARL J. MARTINSON, M.D. MEMORIAL LECTURESHIP ON HEALTH PROMOTION AND DISEASE PREVENTION University of Minnesota

LEONARD SILK MEMORIAL LECTURE Mt.
Desert Island Biological Laboratories

CALDWELL LECTURE
American Roentgen Ray Society

RICHARD H. DENT LECTURE St.
George's School

ROBERT T. WONG DISTINGUISHED PROFESSORSHIP
University of Hawaii, Manoa

NIDA/American Psychiatric Association Obesity Symposium

HARVARD OBESITY COURSE

STANFORD BARIATRIC COURSE

AMERICAN BARIATRIC SOCIETY

RHODES ENDOWED LECTURE

STAFFORD LITTLE LECTURE PUBLIC LECTURES AT PRINCETON

GERALD AND SALLY DENARDO LECTURESHIP, SANTA CLARA UNIVERSITY

ALEX AND LENA CASPER MEMORIAL LECTURE, MIAMI UNIVERSITY

UNIVERSITY OF VERMONT FOOD SYSTEMS LEADERSHIP

GOOGLE LECTURE

GLOBAL STUDIES SYMPOSIUM, WHITMAN COLLEGE
Excellence in Public Service

DONALD DUNPHY LECTURE, MCCONE HOSPITAL, UNIVERSITY OF NORTH CAROLINA

CENTER FOR GLOBAL HEALTH, STANFORD MEDICAL SCHOOL

STANFORD UNIVERSITY: THE ETHICS OF FOOD & THE ENVIRONMENT

STANFORD MEDICAL SCHOOL, DEPARTMENT OF MEDICINE, GRAND ROUNDS

LEGACY WARNER SERIES LECTURE ON IMPACT OF FAMILY AND SMOKING PREVENTION AND CONTROL ACT

LEADING VOICES IN PUBLIC HEALTH, EAST TENNESSEE STATE UNIVERSITY

92ND STREET YMCA PUBLIC LECTURE, NEW YORK

COMMONWEALTH CLUB OF CALIFORNIA

SAN FRANCISCO PUBLIC LIBRARY LECTURE

KANSAS CITY PUBLIC LIBRARY

YALE ROBERT WOOD JOHNSON CLINICAL SCHOLARS PROGRAM

COMMUNITY/PUBLIC SERVICE AWARDS

NATIONAL ASSOCIATION FOR THE ADVANCEMENT OF COLORED PEOPLE
Montgomery County Chapter
Person of the Year

LEAGUE OF WOMEN VOTERS, NEW YORK
Carrie Chapman Catt Award

COMMON CAUSE
Public Service Achievement Award

AMERICAN ACADEMY OF PEDIATRICS
Excellence in Public Service

BUSINESS WEEK
Best in Public Service

GEORGE ORWELL AWARD FOR HONESTY AND CLARITY
IN PUBLIC LANGUAGE
National Conference of Teachers of English

ANTI-DEFAMATION LEAGUE OF B'NAI BRITH
Man of Achievement Five Towns, New York

GOLDEN SLIPPER CLUB OF PHILADELPHIA
Golden Slipper Award

NATIONAL FATHER'S DAY COMMITTEE
Father of the Year Award

UNITED SENIORS HEALTH COOPERATIVE
Seniors Advocate Award

NATIONAL ASSOCIATION OF GOVERNMENT COMMUNICATORS
Communicator of the Year Award

NATIONAL CONSUMERS LEAGUE
Trumpeter Award

THE INTERNATIONAL PLATFORM ASSOCIATION
George Crile Award

AMERICAN LUNG ASSOCIATION of New York
Life and Breath Award in Public Health

CONSUMER FEDERATION OF AMERICA
Philip Hart Public Service Award

CAMPAIGN FOR TOBACCO FREE KIDS
Distinguished Service Award

MEDICAL SOCIETY OF NEW YORK, 1st District Branch
Public Service Award

ONCOLOGY NURSING SOCIETY
Public Service Award

PUBLIC VOICE FOR FOOD & HEALTH POLICY
Special Recognition Award for Advancing the Consumer Interest in Food and Agriculture Policy

ATTENDING PEDIATRICIAN

2003 - 2013	UNIVERSITY OF CALIFORNIA, SAN FRANCISCO MEDICAL CENTER
1997-2003	YALE-NEW HAVEN HOSPITAL
1982-1990	BRONX MUNICIPAL HOSPITAL CENTER
1982-1990	NORTH CENTRAL BRONX HOSPITAL
1982-1990	MONTEFIORE MEDICAL CENTER
1982-1990	HOSPITAL OF THE ALBERT EINSTEIN COLLEGE OF MEDICINE

COMMUNITY ACTIVITIES

SCARSDALE SCHOOL DISTRICT, Scarsdale, New York

1986-1990	Legislative Affairs Advisory Committee 1988-1990 Buildings and Facilities Advisory Committee
1990	SCARSDALE STUDENT TRANSFER EDUCATION PLAN, Board of Trustees

GENERAL INFORMATION

Address:
2715 Steiner Street
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Office Phone:
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Married:
Paulette Kessler
Two children - Elise and Ben

Born:
May 31, 1951

MEDICAL LICENSURE

California
Connecticut (non-active)
Maryland (non-active)
New York (non-active)

PUBLICATIONS

Books

Kessler, David A., CAPTURE: UNRAVELING THE MYSTERY OF MENTAL SUFFERING, Harper, Pub. date: April 2016 Paperback : April, 2017

Kessler, David A. THE END OF OVEREATING: TAKING CONTROL OF THE INSATIABLE AMERICAN APPETITE, Rodale, 2009

Translated and Adapted:

過食にさようなら-止まらない食欲をコントロール [単行本]
K0HEЦ 0бЖ0CTBЖУ
이 페이지 번역하기

Perché mangianmo troppo (e come fare per smetteria
Laat je niet volvreten: Hoe de voedselindustgrie schade toebrengt ann onze gexondheid
Das Ende des groben Fressens Wie die Nahrungsmittelindustrie Sie zu ubermaBigem Essen berleitet und was Sie dagegen tun konnen
Muszáj annyit enni? Hadüzenet a só, a zsír és a cukor ellen
Also: Romania, Canada, UK, Australia, India
Your Food is Fooling You: How Your Brain is Hijacked by Sugar Fat and Salt (US Young Adult Version)
Hijacked: How Your Brain is Fooled by Food (Canadian Young Adult Version)

Kessler, David A., A QUESTION OF INTENT: A GREAT AMERICAN BATTLE WITH A DEADLY INDUSTRY, Public Affairs (Hardcover 2001) (Paperback 2002)

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Naleid, A.M., Grimm, J.W., Kessler, David A., Sipols, A.J., Aliakbari, S., Bennett, J.L., Wells, J., Figlewicz, D.P., "Deconstructing the Vanilla Milkshake: the Dominant Effect of Sucrose on Self-administration Flavor Mixtures," APPETITE, 50(1):128-38 (January 2008)

Halme, Dina J. and Kessler, David A., "FDA Regulation of Stem Cell-Based Therapies", NEW ENGLAND JOURNAL OF MEDICINE, 355 (16): 1730-1735 (October 19, 2006)

Kessler, David A., "Alcohol Marketing and Youth: The Challenge for Public Health," JOURNAL OF PUBLIC HEALTH POLICY, 26(3):292-295 (Autumn 2005)

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Kessler, David A., Barnett, Philip S., Witt, Ann, Zeller, Mitchell R., Mande, Jerold R. and Schultz, William B., "The Legal and Scientific Basis for FDA's Assertion of Jurisdiction Over Cigarettes and Smokeless Tobacco," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 277:405-409 (February 5, 1997)

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Kessler, David A. for the Working Group, "A New Approach to Reporting Medication and Device Adverse Effects and Product Problems," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 269:2765-2768 (June 2, 1993)

Kessler, David A., Taylor, Michael A., Maryanski, James H., Flamm, Eric L., and Kahl, Linda S., "The Safety of Foods Developed by Biotechnology," SCIENCE, 256:1747-1749 (June 26, 1992)

Kessler, David A., "The Basis for the FDA's Decision on Breast Implants,"

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Kessler, David A., "Drug Promotion and Scientific Exchange," NEW ENGLAND JOURNAL OF MEDICINE, 325:201-203 (July 18, 1991)

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Kessler, David A., "Implementing the Anticancer Clauses of the Food, Drug and Cosmetic Act," THE UNIVERSITY OF CHICAGO LAW REVIEW, 44:817-850 (1977)

Kessler, David A., Langer, Robert S., Pless, Naomi A., and Folkman, Judah, "Mast Cells and Tumor Angiogenesis," INTERNATIONAL JOURNAL OF CANCER, 18:703-709 (November 15, 1976)

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Editorials

Kessler, David A., Myers, Matthew, "Beyond the Tobacco Settlement," NEW ENGLAND JOURNAL OF MEDICINE, 345:535-537 (August 16, 2001) (editorial)

Kessler, David A., "Cancer and Herbs," NEW ENGLAND JOURNAL OF MEDICINE, 342 (23):1742-43 (June 8, 2000) (editorial)

Koop, C. Everett, Kessler, David A., Lundberg, George D., "Reinventing American Tobacco Policy - Sounding the Medical Community's Voice," JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION, 279:550-552 (February 18, 1998) (editorial)

Kessler, David A., "Addressing the Problem of Misleading Advertising," ANNALS OF INTERNAL MEDICINE, 116:950-951 (June 1, 1992) (editorial)

Published Speeches

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD AND DRUG LAW JOURNAL, 52:1-5, presented at the Food and Drug Law Institute's 39th Annual Educational Conference, Washington, D.C. (December 10-11, 1996)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD AND DRUG LAW JOURNAL, 51:207-216 (1996), presented at the Food and Drug Law Institute's 38th Annual Educational Conference, Washington, D.C. (December 12-13, 1995)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD AND DRUG LAW JOURNAL, 50:327-334 (1995), presented at the Food and Drug Law Institute's 37th Annual Educational Conference, Washington, D.C.(December 13-14, 1994)

Kessler, David A., "Statement on Nicotine-Containing Cigarettes," TOBACCO CONTROL, 3:148-158 (1994)

Kessler, David A., "Issues in Approving Drugs for AIDS Treatment," REGULATORY AFFAIRS, 6:189-200 (1994), presented at the Institute of Medicine's 25th anniversary lecture series, Seattle, Washington

Kessler, David A., "FDA's Revitalization of Medical Device Review and Regulation," BIOMEDICAL INSTRUMENTATION AND TECHNOLOGY, May/June 1994:220-226, presented at the AAMI/NIH Cardiovascular Science and Technology Conference, Rockville, Maryland (December 10, 1993)

Kessler, David A., "Harmonization," PHARMACEUTICAL ENGINEERING, 14:38-40 (January/February 1994), presented at the Second International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use, Orlando, Florida (October 27, 1993)

Kessler, David A. "The Academic/Industry Interface: The Risks of Scientists Becoming Entrepreneurs," HOPKINS MEDICAL NEWS, Fall 1993:58

Kessler, David A., "Controlled Release and Rational Drug Development," presented at the Controlled Release Society Meeting, July 27, 1993, FOOD AND DRUG REPORTS, 4:9 (1993)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 48:1-10 (1993), presented at The Food
and Drug Law Institute's 35th Annual Educational Conference, Washington, D.C. (December 8, 1992)

Kessler, David A., "Reinvigorating the Food and Drug Administration," FOOD TECHNOLOGY, 46:20 (August 1992), presented at the Annual Meeting of Institute of Food Technologists, New Orleans, LA (June 20-24, 1992)

Kessler, David A., "A Challenge for American Pharmacists," AMERICAN PHARMACY, 33-36 (January 1992)

Kessler, David A., "Remarks--1991 Annual DIA Meeting," DRUG INFORMATION JOURNAL (October 1991)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 46:773-779 (November 1991), presented
at the Association of Food and Drug Officials' Annual Conference, Grand Rapids, MI (June 17, 1991)

Kessler, David A., "Restoring the FDA's Preeminence in Regulation of Food," FOOD DRUG COSMETIC LAW JOURNAL (May 1991)

Kessler, David A., "Remarks Upon Taking the Oath of Office," JOURNAL OF THE ASSOCIATION OF FOOD AND DRUG OFFICIALS, 55:7-10 (April 1991)

Kessler, David A., "Remarks by the Commissioner of Food and Drugs," FOOD DRUG COSMETIC LAW JOURNAL, 46:21-26 (January, 1991), presented at the Food and Drug Law Institute's 33rd Annual Educational Conference, Washington,
D.C. (December 11, 1990)

APPENDIX B: PRIOR TESTIMONY

Dr. David Kessler testified at trial or deposition as an expert in the following cases over more than the last seven years through November 16, 2018:

- ***In re Risperdal***, Philadelphia, PA and Texas cases, including No. 2012CCV-61916-1 (Tex. Dist. Ct. filed Oct. 2, 2012 and Pledger and Walker); Wolken JCCP 4775
- ***Wells v. Allergan, Inc.*** No. 12-973 (W.D. Okla. filed Sept. 4, 2012); ***Drake v. Allergan***, Case No. 2013 vv00234 (U.S. Dist. Ct. Burlington, Vermont)
- ***In re C.R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.***, MDL No. 2187 (S.D.W.V. filed July 15, 2010)
- ***SB v. Ortho-McNeil-Janssen Pharm., Inc. (In re Risperdal Litig.)***, No. 100503629 (Pa. Ct. Com. Pl. filed May 27, 2010)
- ***In re Yaz & Yasmin (Drospirenone) Marketing, Sales Practices & Prods. Lib. Litig.***, MDL No. 2100 (J.P.M.L. filed July 30, 2009)
- ***In re Flonase Antitrust Litigation*** (American Sales Company, Inc. v. Smithkline Beecham Corp.), 08-cv-3149, United States District Court, Eastern District of Pennsylvania
- ***Pharmathene, Inc. v. Siga Techs., Inc.***, No. 2627 (Del. Ch. filed Dec. 20, 2006)
- ***Commonwealth v. Merck & Co.***, No. 09-1671 (Ky. Cir. Ct. filed Sept. 28, 2009) (and Utah)
- ***State v. Merck & Co.***, No. 05-3700 (E.D. La. filed Aug. 5, 2005)
- ***Commonwealth Care Alliance v. AstraZeneca Pharm. L.P.***, No. SUCV2005-269 (Mass. Super. Ct. filed Jan. 25, 2005)
- ***Smith & Nephew, Inc. v. N.H. Ins. Co.***, No. 04-3027 (W.D. Tenn. filed Dec. 17, 2004)
- ***In re Neurontin Marketing, Sales Practices & Prods. Liab. Litig.***, MDL No. 1629 (D. Mass. filed June 9, 2004)
- ***Brown v. Am. Brands, Inc.***, No. 711400 (Cal Super. Ct. filed June 10, 1997)
- ***In re: Actos (Pioglitazone) Prods. Lib. Litig.***, No. 11-md-2299 (W. D. La. filed Dec. 29, 2011)
- ***Brown v RJ Reynolds Tobacco Company et al.***, No. 2007 CA 002855 (Fla. Cir. Ct. filed Nov. 28, 2007)
- ***In re Merck & Co., Inc. Sec., Deriv. & "ERISA" Litig.***, MDL No. 1658, No. 05-2367 (D.N.J. filed May 5, 2005)
- ***In re Prograf Antitrust Ligation*** MDL2242, United States District Court of Massachusetts
- ***In re Nexium Antitrust Litigation*** MDL 2419 United States District Court, District of Massachusetts
- ***Cabana v. Stryker.*** Superior Court of State of California, Los Angeles
- ***In Re: Fosamax Litigation,*** Civil Action No. 282, (Superior Court of New Jersey, Atlantic County) and Case No. 30-2012-00547764 (Superior Court of California, Orange County)
- ***Western Sugar Coop et al v. Archer-Daniels-Midland Co, et al***, U.S. District Court, Central District of California, No. 11-03473
- ***H.B., et al. v. Abbott Laboratories***, No. #15-cv-702-NJR-SCW (U.S District Court, Southern District of Illinois filed June 26, 2015)
- ***In re New England Compounding Pharmacy, Inc. Products Liability Litigation***, MDL No. 2419 (United States District Court of Massachusetts filed 2/14/13)
- ***In re: DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prods. Liab. Litig.***, MDL No. 3:11-md-02244 (N.D. Tex. filed May 24, 2011)
- ***In re: Tropicana Orange Juice Mktg. & Sales Practices Litig.***, MDL No. 2353, No. 2:11-cv-07382 (D.N.J. filed Aug. 10, 2012)
- ***In re Cipro Cases I and II,*** Nos. 4154 & 4220 (Cal. Super. Ct., filed Feb. 25, 2002)
- ***Anders v. Medtronic, Inc., et al.,*** No. 1322-CC10219-02 (Mo Cir. Ct.)
- ***Austin v. C.R. Bard, Inc., et al.***, Case No. 15-cv-8373 (Circuit Court of the 17th Judicial Circuit (Div. 7), Broward County, Florida). ***In re Bard IVC Filters Products Liability Litigation***, Case No. 2:15-MD-02641-DGC.

- ***In re: Zoloft Litigation***, JCCP No. 4771 (Superior Court of California, Orange County)
- ***In re: Testosterone Replacement Therapy Product Liability Litigation***, MDL No. 2545 (U.S. District Court, Northern District of Illinois – Eastern Division)
- ***In re: Xarelto Products Liability Litigation***, MDL No. 2592 (U.S. District Court, Eastern District of Louisiana – New Orleans Division); Philadelphia County Court of Common Pleas
- ***In re: Benicar (Olmesartan) Product Liability Litigation***, Civil No. 15-2606 (U.S. District Court, District of New Jersey)
- ***In re: Cook Medical, Inc. IVC Filters Marketing, Sales Practices and Product Liability Litigation***, MDL No. 2570 (U.S. District Court, Southern District of Indiana – Indianapolis Division)
- ***State of Texas, ex rel. v. AstraZeneca LP, et al.***, Case No. D-1-GN-13-003530 (District Court of Travis County, Texas)
- ***Council for Education and Research on Toxics v. Starbucks Corp***. et al., case number BC435759
- ***In Re Asacol Antitrust (***U.S. District Court for the District of Massachusetts)
- ***United States v. Merck***. ex rel., In re: Merck Mumps Vaccine Antitrust Litigation (U.S.Dist Ct, Eastern District of Pennsylvania)
- ***Blue Cross Blue Shield v GlaxoSmithKline*** (U.S.Dist Ct, Eastern District of Pennsylvania)
- ***Tinsley v. Streich*** (Circuit Court City of Charlottesville, Virginia))

Dr. David Kessler provided sworn expert statements in the following cases over the last five years:

- ***DePuy ASR Hip System Cases***, No. CJC-10-4649 (Cal. Super. Ct. filed Dec. 22, 2010)
- ***Cordero v. Endoscopy Ctr. of S. Nev. LLC (In the Matter of Endoscopy Ctr. & Associated Businesses)***, No. 08-A-558091-C (Nev. Dist. Ct. filed Feb. 28, 2008)
- ***Jenkins et. al. v. Medtronic, Inc. et al.***, Case No. 2:13cv02985 (W.D. Tenn.)

1,000/hr

APPENDIX C: MATERIALS CONSIDERED

LITERATURE:

2015-2020 Excipient Monographs 2 Expert Committee Workplan. 2015. http://www.usp.org/expert-committees/excipient-monographs-2-expert-committee-work-plan

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DEPOSITIONS AND TRANSCRIPTS:

30(b)(6) Deposition and Exhibits of Donald Hicks Taken on 6.28.18 and 6.29.18
30(b)(6) Deposition and Exhibits of John Hopkins Taken on 8.16.18, 8.17.18, 10.17.18, 11.05.18
30(b)(6) Deposition and Exhibits of Joshua Muscat Taken on 9.25.18
30(b)(6) Deposition and Exhibits of Julie Pier Taken on 9.12.18 and 9.13.18
30(b)(6) Deposition and Exhibits of Linda Loretz Taken on 7.17.18, 10.1.18 and 10.2.18
30(b)(6) Deposition and Exhibits of Margaret Gurowitz Taken on 7.12.18
30(b)(6) Deposition and Exhibits of Mark Pollack Taken on 8.29.18
30(b)(6) Deposition and Exhibits of Pat Downey Taken on 8.7.18 and 8.8.18
30(b)(6) Deposition and Exhibits of Robert Glenn Taken on 10.18.18
30(b)(6) Deposition and Exhibits of Susan Nicholson Taken on 7.26.18 and 7.27.18
30(b)(6) Deposition and Exhibits of Tina French Taken on 8.15.18
Carl v. J&J Kemp Hearing Trancript for Curtis J. Omiecinski Dated 08.15.16
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Congressional Testimony 05.14.08 - Pamela Bailey Prepared Statement
Daniels v. J&J Volume 17 Trial Transcript
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Defendants' Motion to Exclude the Testimony of David Steinberg
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Deposition of Joshua Muscat Taken 3.3.2016 in the Hogans v. J&J Matter
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Hogans v. J&J Stipulated Protective Order Dated 1.28.15
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PL's First Amended Master Long Form Complaint in Talc MDL
Protective Order in Hogans, et al. v. J&J, Exhibit A
Ristesund v. J&J Closing Powerpoint

Ristesund v. J&J Trial Transcript Volume 16 (Closing)
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PCPC_MDL00006126
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PCPC_MDL00110545
PCPC_MDL00122041

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PCPC0075385
PCPC0075387
PCPC0075827
PCPC0078446
PCPC0079602
PCPC0080521
PCPC0080710
PCPC0081179
Pltf_JNJ_00000609 (JNJ000021035)
Pltf_JNJ_00001141 (JNJ000011704-11708)
Pltf_JNJ_00003102 (JNJ000024495-24500)
Pltf_JNJ_00003373 (JNJ000020397)
Pltf_LUZ_00000093 (LUZ000566-567)
Pltf_LUZ_00000419 (LUZ003204)
Pltf_LUZ_00000647 (LUZ005090-5091)
Pltf_LUZ_00000899 (LUZ006056)
Pltf_LUZ_00005093 (LUZ011963)
Pltf_LUZ_00008807 (LUZ022207-22208)
Pltf_PCPC_0002036 (PCPC0077761-7926)
Pltf_JNJ_00031488 (JNJ000240311)
Products _ Hair-Smoothing Products That Release Formaldehyde When Heated
Profit Opportunity - Adult market JNJ BP
Response to Public Citizen request 1.11.1979 Redacted
Responses to Russell on Particles in Talc
Steve Gettings - Vice-President Global Product Safety & Regulatory Affairs
The Birth of Our Baby Products Kilmer House
Van Tibolli Beauty Corp 9.2.15
WCD – Krempecki (NJ) - 00005
WCD000001
WCD000016
WCD000039
WCD000067
WIND-MA10764-0001